IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, Plaintiff, v. MEDTRONIC VASCULAR, INC. and BOSTON SCIENTIFIC CORPORPORATION, Defendants.	)	**REDACTED PUBLIC VERSION** C.A. No. 97-550-SLR

CORDIS'S COMBINED REPLY BRIEF IN SUPPORT OF ITS MOTION FOR ENTRY OF FINAL JUDGMENT AND ANSWERING BRIEF IN OPPOSITION TO BSC'S CROSS-MOTION TO DEFER FURTHER PROCEEDINGS AND FOR A NEW TRIAL

ASHBY & GEDDES
Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Tiffany Geyer Lydon (I.D. #3950)
500 Delaware Avenue - 8th Floor
P.O. Box 1150
Wilmington, DE 19899
302-654-1888

Attorneys for Plaintiff Cordis Corporation

Of Counsel:

Gregory L. Diskant
Eugene M. Gelernter
Michael J. Timmons
Scott B. Howard
Kathleen M. Crotty
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036

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Cordis respectfully submits this combined brief: (a) in reply on its motion to enter final judgment against Medtronic and BSC, and (b) in opposition to BSC's cross-motion to defer further proceedings and for a new trial on obviousness.

INTRODUCTION

The first rule of the Federal Rules of Civil Procedure provides that the rules shall be administered "to secure the just, speedy and inexpensive determination of every action." Fed. R. Civ. P. 1. This case has been anything but, and it is now time to draw it to a close. No one would contend that these proceedings – going back to 1997 – have been either speedy or inexpensive. Meanwhile, Cordis has prevailed again and again – either at trial or on appeal – and yet, thanks to the defendants' seemingly endless delaying tactics, the case has dragged on for over a decade. In the interim, Cordis' pioneering '762 patent expired, denying Cordis the opportunity for an injunction or even the ability to negotiate a favorable cross-license with the defendants under the threat of an injunction.

Cordis filed these cases in 1997. In 1998 – ten years ago – this Court denied Cordis' request for a preliminary injunction against co-defendant Guidant. It ruled, "Mindful that a different judicial officer could well conclude otherwise, the court shall make every effort to expedite trial on the merits so as to minimize the impact of this decision." D.I. 284 at 26.

But progress has been slow. In 2000, Cordis settled with Guidant in return for access to Guidant's valuable rapid exchange technology and in 2003 an arbitration panel ruled that Guidant had infringed the valid '762 patent, awarding Cordis $425 million in damages. In federal court, however, BSC and Medtronic have applied what Learned Hand called, in a somewhat different context, "the antlike persistency of [patent] solicitors," *Lyon v. Boh*, 1 F.2d 48, 50 (S.D.N.Y. 1924), *rev'd on other grounds*, 10 F.2d 30 (2d Cir. 1926). They have dragged

this case through unnecessary trials and motion practice, advocating meritless positions and building substantial stent businesses in willful disregard of Dr. Palmaz's ground breaking invention. But the end is now in sight. The Court can now measurably advance this litigation and afford some measure of justice to Cordis. On remand from the Federal Circuit, this Court should promptly reinstate the verdicts and allow a final appeal on the damages verdict.

But BSC and Medtronic continue to resist. To quote Learned Hand again, they resort to "needless elaboration of distinctions which are verbal and details which are trivial," *id.* at 49, hypothesizing fanciful rationales why a jury might have found the changed definition of "smooth" to be the key to the validity of claim 23 and the changed definition of "slots formed therein" to be the key to claim 44.

Common sense, fairness and legal authority all suggest that this Court should firmly and promptly reject these efforts. This Court has presided over four liability trials and two damages trials against these defendants. It knows exactly why Cordis prevailed on its validity case: Dr. Palmaz's invention was a dramatic advance in cardiology. He provided a non-surgical intraluminal treatment for cardiac disease, a field of endeavor that this Court has recognized is "antithetical" to Ersek's work in open surgery. He created a controllably expandable and plastically deformable stent, a novel concept never dreamed of even by scientists already working with intraluminal devices. He designed the optimal design for a stent, using longitudinal slots, vastly better than the competing coil stents and the hallmark of every commercially successful stent.

These features are all claimed in his patent and none of them has anything to do with the claim terms whose definitions have changed. Indeed, for claim 23, making a stent expressly smooth enough for intraluminal delivery, as the claim definition now provides, makes

the invention even more antithetical to Ersek. And, for claim 44, although the method of formation of the slots is immaterial to the novelty of the invention, Ersek had "slots formed therein" under either definition. Based on this Court's "intimate familiarity" with the record, this Court can, and should, find it "highly probable" that any error in claim construction was harmless. It should enter judgment for Cordis and help bring this case to its final conclusion.

I. This Court Should Promptly Enter Judgment

Typically, both BSC and Medtronic argue for more delay. But there is, as the Supreme Court has noted, an "obvious desirability of bringing to a close this already prolonged proceeding." *Federal Power Comm'n v. Sunray DX Oil Co.*, 391 U.S. 9, 39 (1968).

Having lost on all their other theories, defendants now pin their hopes on the argument that two Monographs written by Dr. Palmaz in 1980 and 1983 will someday be ruled to be prior art, leading to a new round of trials. Such a ruling is extremely unlikely. The Monographs are not prior art, as this Court observed in denying BSC's motion for summary judgment in the Express case, action 03-027. Exhibit M at 12.

But in any event, it is hard to see how such a ruling could help defendants here. Both defendants identified the Palmaz Monographs as § 282 art in the 2000 trial and yet did not rely upon them to present an invalidity case. When given another opportunity to try invalidity in 2005, neither defendant sought to rely upon the Monographs in their experts reports or pleadings. On the eve of trial in early 2005, however, both defendants raced into court seeking permission to expand their invalidity case to include the Palmaz Monographs. This Court properly denied this motion as untimely, D.I. 1326 at 14-16, and neither defendant claimed on appeal that the denial was error. The Palmaz Monographs are not part of this case.

But something pernicious is going on. BSC is playing this Court against the Court of Appeals. In this Court, BSC argues that the Court should delay ruling in the hopes that

the Federal Circuit will determine in the Express case – which involved BSC's second generation stents and which is now on appeal to the Federal Circuit – that the Palmaz Monographs are printed publications, and therefore prior art. Yet that issue is not likely to be addressed in the Express case. In the Express case, BSC attempted to use the Palmaz Monographs as an invalidity defense and it moved for summary judgment on the issue. This Court denied the motion, observing "the Palmaz Monographs are not prior art under § 102(b)." Exhibit M at 12.

The reason the Court of Appeals is unlikely to address whether or not the Monographs are printed publications is because this Court correctly precluded BSC from making any validity challenge to claim 23 – based on the Palmaz Monographs or anything else – because of collateral estoppel. Exhibit M at 17. BSC had already tried and lost its contention that claim 23 was invalid in this case. The Court expressly permitted BSC to raise a validity challenge to claim 1, Exhibit M at 15, but BSC thereafter waived that challenge. As a result, the Federal Circuit should affirm the validity ruling on claim 23 based on collateral estoppel and the ruling on claim 1 based on waiver. The status of the Palmaz Monographs will most likely never be addressed.

Yet in the Federal Circuit, BSC argues that this Court's collateral estoppel ruling should be set aside on appeal in the Express case because on ***this remand motion*** this Court ***might*** set aside the validity verdict in this case because of the change in the "smooth" limitation. It argues this judgment is not final because "[e]ven today, the NIR validity judgment is on remand for consideration of a new trial in light of the broadened construction of 'smooth surface.'" Exhibit N at 40.

In short, BSC is trying to have it both ways. On appeal, it is using the fact that this motion is pending to try to defeat this Court's collateral estoppel ruling in the Express case.

If BSC actually thought it would win this motion, it would ask this Court to expedite its ruling, since a win here would help BSC's argument on appeal. But instead it is asking this Court to delay ruling on this motion, obviously recognizing that it is highly likely to lose and that denial of this motion will doom its appeal in the Express case.

This gamesmanship is inappropriate. If this Court rules that BSC is ***not*** entitled to a new obviousness trial because of the change in the "smooth" limitation, then BSC's argument against the Court's collateral estoppel ruling in the Express case evaporates and the Federal Circuit will undoubtedly affirm. The result will be no new trial in this case and no new trial in the Express case.

BSC argues that it would "waste judicial resources" to rule on this motion before the Federal Circuit decides the status of the Palmaz Monographs. The true waste of judicial resources would be to delay ruling on this motion and thereby open the door to two unnecessary new trials, one in this case and one in the Express case. This Court can measurably advance the resolution of ***both*** cases – and avoid a waste of judicial resources – by ruling on this motion. The proper ruling, we submit, is a denial of the defendants' request for a third liability trial. This Court will protect itself from mischief in the Federal Circuit by acting promptly.

Defendants present other reasons for delay, all meritless. Both ask for a stay pending reexamination of the '762 patent. D.I. 1462 at 7, n.6; D.I. 1460 at 16. The '762 patent is being reexamined as a result of requests filed by Medtronic and BSC in 2005 and 2007 – after they lost their validity case at trial. But there is no basis to delay entry of final judgment after a trial and appeal simply because there is a reexamination proceeding pending that may take many more years to complete. In this procedural setting, the "likely time frame and outcome of the PTO reexamination process is merely speculation. This court cannot and will not grant

[defendant] the extraordinary remedy of delaying these proceedings any further than they already have been based on conjecture." *NTP, Inc. v. Research in Motion, Ltd*, 397 F. Supp. 2d 785, 788 (E.D. Va. 2005); *see also Viskase Corp. v. American Nat'l Can Co.*, 261 F.3d 1316, 1327-28 (Fed. Cir. 2001) (affirming denial of stay when defendant sought reexamination after trial).

Finally, Medtronic argues (D.I. 1460 at 17) that entry of judgment should be delayed because of the potential for inconsistent findings between this case and a second case, action 98-80, in which Medtronic was found to infringe ACS' Lau patents. But Cordis is not a party to the action, so the potential for inconsistent verdicts on damages issues does not exist. Moreover, the fact that Medtronic is a serial infringer and may owe several companies royalties and lost profits has no bearing on the damages award in this case and provides no basis for not entering judgment.

The defendants apparently aspire to a series of never-ending trials. But "additional proceedings are pointless," and the time has come for "the court [to] bring the case to a close." *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1368 (Fed. Cir. 1997); *see also Kenney v. California. Tanker Co.*, 381 F.2d 775, 777 (3d Cir. 1967) (district courts should exercise their power "'to prevent undue delays in the disposition of pending cases ....'"), quoting *Link v. Wabash R.R.*, 370 U.S. 626, 629 (1962).

II. The Harmless Error Standard

On appeal in *Cordis Corp. v. Medtronic AVE, Inc. and Boston Scientific Corp.*, 511 F.3d 1157 (Fed. Cir. 2008) ("*Cordis II*"), BSC argued that it was "entitled" to a new trial on validity if the Court changed the construction of "smooth" in claim 23 or if the Court reversed BSC's judgment on claim 44 under the earlier construction of "slots formed therein."

The Federal Circuit rejected the argument that these changes "entitled" BSC to new trials on obviousness. *Cordis II*, 511 F.3d at 1180. Instead, the Federal Circuit recognized

that this Court is in the best position to determine – "in light of [its] intimate familiarity" with the record – whether the changes in claim construction "require[] any further proceeding with respect to the issue of obviousness." *Id.*; *see also Cordis Corp. v. Boston Scientific Corp.*, 2008 WL 1777441 (Fed. Cir. April 9, 2008).

Defendants admit that this Court must resolve this question on remand by applying the harmless error standard. *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1332-33 (Fed. Cir. 2008); *Teleflex, Inc. v. Ficosa N. America Corp.*, 299 F.3d 1313, 1328-29, 1334 (Fed. Cir. 2002). In light of the overwhelming proof of the nonobviousness of Dr. Palmaz's invention, the error in the claim constructions under which these cases were tried is indeed harmless. Effectively acknowledging as much, defendants distort beyond all recognition the harmless error inquiry. As BSC and Medtronic see it, the question is whether a jury "could" have reached a different result under an increasingly fanciful set of hypotheticals. But the juries "could" have done anything – we will never know what happened in the jury room and that knowledge is not, and cannot be, part of the harmless error analysis. Rather, under Third Circuit law, which controls this issue,[1] application of the harmless error rule requires "perforce [a] resort to probabilities." *Government of the Virgin Islands v. Toto*, 529 F.2d 278, 283 (3d Cir. 1976).

Thus, in applying the harmless error rule, the court does ***not*** need to rule out "every reasonable possibility of prejudice." *Ballay v. Legg Mason Wood Walker, Inc.*, 925 F.2d 682, 694 n.15 (3d Cir. 1991); *see also General Motors Corp. v. New A.C. Chevrolet, Inc.*, 263 F.3d 296, 329 (3d Cir. 2001) (same). It does ***not*** have to conclude with "almost certain[ty]" that

[1] In patent cases, the question of whether a claim construction error is prejudicial or harmless is a matter governed by "the law of the regional circuit." *Finisar*, 523 F.3d at 1328; *see Northpoint Tech., Ltd. v. MDS America, Inc.*, 413 F.3d 1301, 1310-11 (Fed. Cir. 2005) ("Because the right to a new trial is a procedural issue not unique to patent law, the applicable law is the law of the regional circuit ....").

the error did not affect the judgment. *McQueeney v. Wilmington Trust Co.*, 779 F.2d 916, 924 (3d Cir. 1985), quoting *Toto*, 529 F.2d at 283.

Rather, the court must decide, "***in light of the entire record***, [whether] it is ***highly probable*** that the jury would have returned the same verdict … if it had been correctly charged." *Bates v. Board of Ed. of the Capital School Dist.*, 2000 WL 376405, *6 (D. Del. Mar. 31, 2000) (Robinson, J.) (emphasis added); *see also Goodman v. Pennsylvania Turnpike Comm'n*, 293 F.3d 655, 667 (3d Cir. 2002) ("[W]e ask whether it is 'highly probable' that the jury would have reached the same verdict absent the alleged [error]."); *Pivirotto v. Innovative Sys., Inc.*, 191 F.3d 344, 358 (3d Cir. 1999) ("[W]e believe that… it is highly probable that the jury would have returned the same verdict even if it had been charged on the correct formulation …."); *Hurley v. Atlantic City Police Dep't*, 174 F.3d 95, 112 (3d Cir. 1999).

III. There Is No Basis for New Trials on Obviousness

A. The Federal Circuit's Mandate Forecloses a New Obviousness Trial for Medtronic

Although this Brief responds to both defendants' new trial arguments, BSC is the only defendant that preserved such arguments on appeal and the only defendant that is entitled to raise them on remand. *Cordis II* defeats Medtronic's motion for a new trial on obviousness.

Cordis II was a single appeal involving both defendants. In its response brief in *Cordis II*, Cordis answered BSC's *Festo* arguments by suggesting, as an alternate ground for affirmance, that BSC's NIR stent would *literally* infringe under a functional definition of "smooth," meaning smooth enough for intraluminal delivery. Medtronic and BSC then filed reply briefs in the Federal Circuit. In their respective reply briefs, BSC responded by asking the Federal Circuit to order a new obviousness trial if it adopted the functional construction of "smooth"; Medtronic never mentioned the issue.

Medtronic now argues (D.I. 1460 at 10) that it "had no reason or opportunity to respond" to Cordis' suggestion that the Federal Circuit adopt a functional definition of "smooth." But Medtronic had the exact same reason and opportunity to respond as BSC. The "reason" for Medtronic to respond – same as for BSC – was to preserve the issue if it wanted the chance to address it later. Medtronic's "opportunity" to do so – again same as for BSC – came in its reply to the brief filed by Cordis and in oral argument in the Federal Circuit. Yet it said nothing on the subject, undoubtedly because the change would not in any event affect its adverse verdicts on the '984 patent.

The first time Medtronic asked for a new trial on this issue was in response to this motion by Cordis. By then, it was too late. The Federal Circuit's mandate had issued and on appeal the Court rejected every argument that Medtronic raised on obviousness. Medtronic argues (D.I. 1460 at 9) that only issues "actually decided" on appeal are foreclosed from consideration on remand. That is plainly not correct; a final judgment affirmed on appeal is final. But, in fact, the issues "actually decided" in *Cordis II* included Medtronic's assertion that it was entitled to a new trial on obviousness. The Federal Circuit rejected the arguments Medtronic presented on this subject in the clearest possible terms: "Medtronic has not remotely demonstrated that it is entitled to a new trial on obviousness." *Cordis II*, 511 F.3d at 1172. For Medtronic, that is the end of the matter.

B. The Nonobviousness of the '762 Invention Was Established by Overwhelming Evidence

In deciding the harmless error issue, this Court must take into account the record in its "entirety." *Kotteakos v. United States*, 328 U.S. 750, 762 (1946). That is precisely what the Federal Circuit asked this Court to do "in light of [its] intimate familiarity" with the record. The entire record, needless to say, consists of all the evidence presented by both sides. After

four liability trials and two damage trials, this Court is uniquely well suited to evaluate whether the two changes in claim construction had any bearing on the outcome of this case. We respectfully submit that the evidence of the nonobviousness of claim 23 was simply overwhelming. It is "highly probable" that the jury would have reached the same conclusion on claim 23 under the new definition of "smooth." Likewise, the definition of "slots formed therein" was immaterial to BSC's conscious decision to waive a validity challenge to claim 44 and the change in construction does not excuse it from that waiver.

This is a rare case. The typical patent case involves an incremental improvement of debatable utility. In this case, the invention is genuinely exciting and critically important: Dr. Palmaz's balloon expandable stent was revolutionary and pioneering. It transformed medical practice and revolutionized the treatment of coronary artery disease.

In the late 1970s and 1980s, coronary artery disease was the leading cause of death in the United States. D.I. 1369 at 153:2-9; D.I. 1387 at 260:3-17. Conventional surgeons, such as Dr. Ersek, employed open heart surgery, which was highly intrusive and dangerous. D.I. 1369 at 154:13-156:7; D.I. 1387 at 262:16-265:2. The science of interventional cardiology was just developing. Dr. Charles Dotter, a legendary pioneer, created the concept of intraluminal delivery in 1969, but his particular invention was to use a fixed diameter cylinder to force open a closed artery. D.I. 1370 at 372:24-374:4; D.I. 1388 at 668:18-670:11. The idea never succeeded. In 1977, Dr. Andreas Gruntzig invented balloon angioplasty, which was the first major advance since Dotter. Gruntzig used Dotter's idea of intraluminal delivery to place an expandable balloon at the site of the diseased artery. The balloon was expanded, opening the artery, and it was then withdrawn. D.I. 1370 at 374:5-21; D.I. 1388 at 668:18-670:21. An

improvement to be sure, but neither Dotter's idea nor Gruntzig's provided any permanent solution.

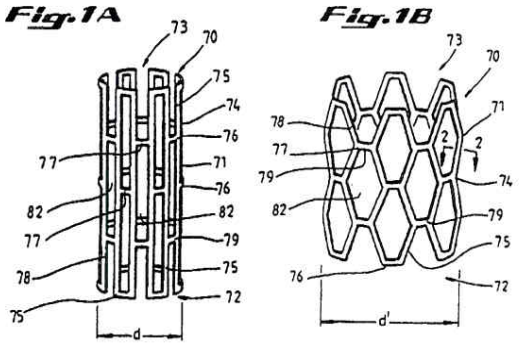
Innovators in the field of intraluminal procedures – the best minds in medicine – actively searched for a better solution. They considered a host of alternatives, including rotor-rooter type devices, heated balloons, hot tipped lasers, and so on. D.I. 1370 at 377:11-380:13; D.I. 1388 at 630:6-634:20. But these ideas, like Gruntzig's, shared a common feature – they avoided leaving behind a permanent implant in the heart. The conventional wisdom – even among the select scientists working in intraluminal delivery – was that leaving a metal device in the heart was dangerous, indeed ridiculously so. D.I. 1370 at 380:14-384:2; D.I. 1388 at 635:8-638:23. These concerns were heightened in the 1980s because of experience with the Shiley heart valve, which caused "a very large number of deaths." *Id.*

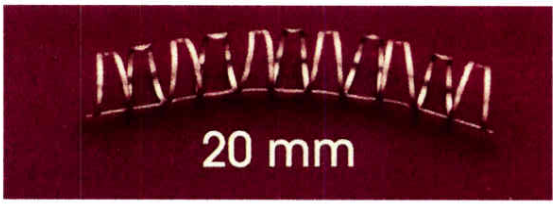
A few pioneers nonetheless considered permanent implants. Dr. Caesar Gianturco, Dr. Palmaz's competitor in the search for an improvement over angioplasty, created self-expanding Z-stents, which were left permanently behind in the heart and delivered intraluminally. But the Z-stents could not be controlled. They popped open with spring force and so could easily wind up too big or too little, either a dangerous outcome. D.I. 1370 at 384:13-387:20; D.I. 1388 at 638:24-643:16. Meanwhile, skepticism about implants of any sort was only heightened by published reports that the self-expanding stent developed by Dr. Hans Wallsten caused "real problems with thrombosis and a very high complication rate," leading *The New York Times* to give stents a "failing grade." D.I. 1370 at 389:11-390:24; D.I. 1388 at 645:22-647:12.

If those engaged in intraluminal procedures were pioneers, and those willing to leave a device behind in the heart were cutting-edge pioneers, in that small group of elite

scientists, Dr. Palmaz stood alone. Rejecting self-expanding stents as impractical and dangerous, he had a breakthrough insight – Gruntzig's angioplasty balloon could be used to controllably expand and plastically deform a metal scaffold inside the heart. By using the balloon, the scaffold could be expanded to precisely the right size. This is the idea – simple, but brilliant – behind the balloon-expandable stent.

Dr. Palmaz had one further insight that proved critical to the development of the stent. In addition to conceiving the idea of the balloon-expandable stent, he also conceived the optimal design for a stent. The stent would be composed of circumferential rings that could be added or subtracted to create a stent of whatever length one wished. The key to the ring was its use of longitudinal slots, openings that are longer than they are wide running in a longitudinal direction along the length of the stent. The longitudinal slots permitted the ring to expand circumferentially to create an expanded ring of great radial strength. The brilliance of this design was demonstrated only afterwards when Dr. Palmaz's rival, Dr. Gianturco, turned to balloon-expandable stents himself. Dr. Gianturco then designed the Gianturco-Ruben coil stent, in which the slots were arranged vertically, rather than longitudinally, creating a coil like device that opened like a clam shell. This alternative design lacked the radial strength of Dr. Palmaz's longitudinal slots. It collapsed in patients and proved a disaster in the marketplace. D.I. 1370 at 320:6-321:12; D.I. 1388 at 648:16-649:21.





These three ideas taken together – intraluminal delivery, controllable expansion and plastic deformation, and longitudinal slots – are the critical concepts embodied in Dr. Palmaz's '762 patent. But the invention story only gets better, embracing every secondary indicia of nonobviousness, one after another. In the beginning, no one would buy Dr. Palmaz's idea. In the early 1980s, company after company turned Dr. Palmaz away. They thought his idea was too risky and potentially dangerous. D.I. 1369 at 216:2-217:2; D.I. 1387 at 330:3-331:12. Even when Johnson & Johnson invested huge sums in developing a product and sponsoring the Stress and Benestent studies – the largest clinical studies that ever had been conducted of a medical device – skepticism persisted. D.I. 1370 at 317:7-17; D.I. 1387 at 433:11-23. As late as 1991, six years after Dr. Palmaz's filing date, an editorial in *The New England Journal of Medicine* concluded that efforts to develop stents were "probably futile." D.I. 1370 at 393:22-395:10; D.I. 1388 652:12-654:20.

Three years later, the results of Stress and Benestent were published in *The New England Journal*. They showed that the stent of Dr. Palmaz's invention is safe and significantly more effective than balloon angioplasty. D.I. 1370 at 397:20-403:4; D.I. at 1388 at 662:10-20. The FDA approved the Palmaz-Schatz stent on an expedited basis one month later. Cordis then introduced its Palmaz-Schatz stent, which broke all records for sales of a medical device, with sales of $500 million in its first two years on the market. D.I. 1370 at 318:18-319:24; D.I. 1387 at 442:24-445:21. In 1997, the medical device industry, with the participation of BSC, recognized the Palmaz-Schatz stent as the most successful medical device introduced in the prior fifteen years. D.I. 1370 at 322:10-323:4; D.I. 1387 at 445:22-446:18.

Stenting soon replaced balloon angioplasty as the primary intervention for coronary artery disease, D.I. 1369 at 166:17-169:7; D.I. 1387 at 284:6-286:5, and a "frenzy of

activity" then pervaded the medical device industry. D.I. 1370 at 400:20-402:8; D.I. 1388 at 659:24-661:9. Companies that had spurned Dr. Palmaz sought to cash in on his ideas. Some companies took licenses from Cordis. D.I. 1370 at 330:6-331:3; D.I. 1387 at 458:18-459:19. Others, such as BSC and Medtronic, gambled that the financial gains from infringement might outweigh the cost. *Id.*

As new stents entered the market, the market for stents practicing Dr. Palmaz's invention kept growing, reaching $3 billion annually by early 2005. D.I. 1370 at 321:13-16; D.I. 1387 at 444:16-21. Dr. Palmaz's work "led to a huge industry of companies all producing devices which … use Dr. Palmaz's invention." D.I. at 1370 487:18-488:5; *see also* D.I. 1388 at 666:18-667:18. "All of the successful market leading stents use the teachings … [of] Claim 23 [of] the '762 patent." D.I. 1370 at 487:18-488:18; *see also* D.I. 1371 at 704:12-705:16; D.I. 1388 at 796:12-800:12.

Dr. Palmaz's invention has "been rightly credited the world over." D.I. 1370 at 488:6-13; *see also* D.I. 1389 at 968:13-23 . Dr. Palmaz has won numerous awards for his work. D.I. 1369 at 231:20-236:20; D.I. 1387 at 362:14-366:24. His early prototypes are in the Smithsonian Institution in Washington, D.C. D.I. 1369 at 236:25-237:8; D.I. 1387 at 367:1-10.

Dr. Palmaz's monumental achievements created an insurmountable problem for defendants challenging the validity of his invention. In fact, both sides' experts had only praise for Dr. Palmaz and his work. Thus, Cordis expert Dr. Tim Fischell ranked Dr. Palmaz as "one of the top two or three pioneers in the field of cardiovascular medicine," D.I. 1369 at 173:11-17, and described his balloon expandable stent as "one of the biggest breakthroughs in the history of interventional cardiology, probably the biggest in the last 25 years." D.I. 1387 at 289:6-290:22. Dr. Howard Hermann, who authored a leading text on the Palmaz-Schatz stent, testified to the

same effect. D.I. 959 at 301:9-24. Dr. Nigel Buller described Dr. Palmaz's contribution as "enormous"; it has "completely changed the way we practice cardiology for treating patients with coronary artery disease." D.I. 1370 at 403:16-404:14.

Defendants were no less glowing. In the 2005 trial, Medtronic's expert, the eminent cardiologist Dr. Richard Heuser, called Dr. Palmaz's work "pioneering" and described it as "breakthrough technology." D.I. 1390 at 1567:4-24. He agreed that Dr. Palmaz's invention of the balloon-expandable stent could "fairly be called a modern medical miracle." *Id.* At trial in 2000, another Medtronic expert, Dr. Rodney Badger, agreed that Dr. Palmaz's invention "revolutionized" medicine and represents a "[m]ajor advance in medical history." D.I. 964 at 1696:11-18. During the preliminary injunction hearing in 1998, Dr. Thomas Linnemaier, an eminent cardiologist who was the expert for defendant ACS, agreed that Dr. Palmaz is a "pioneer" and that his work "revolutionized" the practice of cardiology. D.I. 168 at 929:13-19. At trial in 2005, BSC's counsel praised Dr. Palmaz's "idea of putting the stent on a balloon, delivering it intraluminally" as a "great idea," one that Dr. Palmaz is "entitled to credit for … and he has received it in spades." D.I. 1369 at 127:17-19, 127:23-128:6.

The trial record thus demonstrated that Dr. Palmaz's invention, as embodied in claim 23, was a dramatic and nonobvious advance over the prior art. The innovation of an intraluminally deliverable device that was controllably expandable and plastically deformable was unlike anything known to science. Combining those ideas with a design featuring longitudinal slots transformed medical practice. Not only was claim 23 nonobvious over the prior art, but the secondary considerations of nonobviousness were overwhelming and unrebutted: (1) long felt need; (2) failure of others; (3) proceeding contrary to the accepted

wisdom; (4) initial skepticism; (5) unexpected results; (6) praise; (7) commercial success; and (8) licenses.

One can search high and low without finding another patent case with this kind of invention story. The record leaves no doubt that Dr. Palmaz stands proudly with Dr. Charles Dotter and Dr. Andreas Gruntzig in the pantheon of pioneers who have shaped modern interventional cardiology. D.I. 1370 at 372:11-375:4; D.I. 1388 at 668:18-669:24.

C. The Legal Record Establishes the Case on Obviousness Was Not Close

Most experienced patent litigators have never encountered an invention of such importance. The ability to challenge it was daunting and, while defendants did what they could, they were crushed by the unrebutted evidence. Perhaps wishfully, BSC asserts that this case "has been extremely close." D.I. 1462 at 3. With respect to defendants' obviousness challenge, the legal record demonstrates the opposite.

Defendants cite snippets from the prosecution history of the '762 patent, but they ignore the Examiner's ultimate – remarkable – conclusion. After reviewing all the cited references, including both Ersek and the Palmaz Abstract, he wrote: "None of the references of record, whether considered separately or in any combination, can be used to properly reject any of the claims as they now stand." Ex. O at PWRAP 3260. The underlining is by the Examiner, acknowledging the remarkable invention he was considering. Moreover, his conclusion is all the more striking because he was acting prior to claim construction and so, consistent with his duty, was giving the claim terms their broadest reasonable construction. *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000).

The defendants, by their actions, have also acknowledged the towering achievement of this invention. In the first round of trials in 2000, neither Medtronic nor BSC

raised an obviousness defense. In high stakes litigation, that waiver speaks volumes. Only in the re-trials in 2005, with their backs to the wall, did BSC and Medtronic assert that the '762 patent was obvious – and both lost resoundingly.

Thereafter, in this Court, Medtronic and BSC argued for a new obviousness trial on the grounds that the verdicts of nonobviousness were against the weight of the evidence. This Court rejected the arguments and, on appeal, neither defendant challenged that ruling. On appeal, Medtronic's only obviousness argument was a challenge to the jury instructions. The Federal Circuit gave that argument short shrift, concluding that "Medtronic has not remotely demonstrated that it is entitled to a new trial on obviousness." *Cordis II*, 511 F.3d at 1171-72. BSC's only obviousness argument was a challenge to evidentiary rulings, which the Federal Circuit likewise rejected. *Id.* at 1183-84.

After presiding over four jury trials on liability in which Cordis presented overwhelming evidence of nonobviousness, this Court can conclude with great certainty that it is "highly probable" that the changes in claim construction could not have affected the outcome. The evidence of nonobviousness is crushing, essentially incontestable. There is nothing in the legal record of this case that remotely challenges that conclusion.

D. The Proof of Nonobviousness Is Not Changed by the Change in Claim Construction

At trial in 2005, Cordis focused on the three critical features – intraluminal delivery, controllable expansion and plastic deformation, and longitudinal slots – that, in combination, made Dr. Palmaz's invention utterly unlike the prior art. D.I. 1373 at 1307:12-1308:22; D.I. 1391 at 1864:17-1865:12. And it focused on the overwhelming, almost unheard of, secondary considerations of nonobviousness. None of this evidence was affected in any way by the change in claim construction.

The critical claim limitations requiring intraluminal delivery, controllable expansion and plastic deformation, and longitudinal slots are contained in both claim 23 and claim 44, and their construction has never changed. It is these limitations that, taken together, define the path-breaking invention of Dr. Palmaz. It does not matter to the brilliance of his invention whether his stent is smooth to the touch, or smooth enough for intraluminal delivery. It does not matter to the brilliance of his invention whether slots are formed by removal of metal from a tube, or by any other conventional matter. In the context of this great invention, those are just "distinctions which are verbal and details which are trivial." *Lyon*, 1 F.2d at 49.

The secondary considerations of nonobviousness are likewise unchanged. The definition of "smooth" or of "slots formed therein" has nothing whatever to do with the long-felt need to improve the treatment of cardiac disease or the failure of others to do so, with the skepticism with which the medical community initially responded to Dr. Palmaz's invention or with the pride of its eventual embrace. Those definitions have nothing to do with the staggering commercial success and licensing of devices that practiced the invention, with the copying of Dr. Palmaz's work by others or with the praise that Dr. Palmaz has received for his work. All that is unchanged by the change in claim construction.

Defendants argue that the changes in claim construction nonetheless make two pieces of prior art more relevant: Ersek and the Palmaz Abstract. In fact, those references were unquestionably deemed irrelevant by the jury because they each lacked one of the critical components of Dr. Palmaz's invention. Ersek was irrelevant because it was not intraluminally deliverable and instead was an open surgical device. The Palmaz Abstract was irrelevant because it did not disclose a controllably expandable and plastically deformable stent, and

instead seemed to be just another self-expanding stent. This Court is in a position to know that from having presided over the trial and should say so with certainty now.

1. Ersek Is Not Intraluminally Deliverable

The device of Dr. Palmaz's invention is intraluminally deliverable, *i.e.*, it is suitable for delivery from a remote location through the vascular system without surgically exposing the area to be treated. Exhibit P at 1:30-37. Devices for intraluminal delivery are fundamentally different from devices for conventional open surgery, such as Ersek. As this Court has recognized, "[c]learly the structure of the Ersek device is ***the antithesis***" of an intraluminally delivered stent. D.I 1251 at 10-11, quoting PWRAP 3061-62 (emphasis added).

The trial evidence supporting this conclusion is overwhelming – and unrelated to one definition of "smooth" versus another. Devices for conventional open surgery, such as the Ersek device, have "nothing to do with Dr. Palmaz's invention. This is in a completely different art." D.I. 1370 at 493:19-494:9; *see also* D.I. 1388 at 742:15-743:7. As a result, Ersek is not analogous art. D.I. 1370 at 494:12-15; D.I. 1388 at 742:19-22. "Ersek is teaching a surgical procedure where you've opened the patient up, you're operating on them, you're removing parts, replacing parts." D.I. 1370 at 508:1-6; *see also* D.I. 1388 at 745:24-746:11. "Ersek is the antithesis" of Palmaz. D.I. 1370 at 503:6-17; D.I. 1388 at 774:4-17; *see generally* D.I. 1370 at 492:21-511:20; D.I. 1388 at 740:17-784:21.

Thus, Cordis overwhelmingly demonstrated that Ersek has no bearing on Dr. Palmaz's invention. The Ersek device is a "surgical stapling device to replace the surgeon's sutures." D.I. 1370 at 494:1-9; *see also* D.I. 1388 at 752:21-753:11. To serve its intended purpose as a substitute for sutures, the Ersek device has a "multitude of narrow projecting edges," which give it a "saw-tooth appearance" and "act as a stapler … [to] join together whatever you are putting into the body." D.I. 1370 at 498:1-19; *see also* D.I. 1388 at 749:5-20.

"These sharp metal projecting and penetrating edges are a fundamental requirement for the successful operation of the [Ersek] sleeve." D.I. 1370 at 506:19-507:8; D.I. 1388 at 775:3-16..

Ersek's sharp, outwardly projecting edges prevent it from being used for "intraluminal[ ] deliver[y] as that term is understood by those skilled in the art." D.I. 1370 at 507:15-508:6; D.I. 1388 at 776:8-777:4. "No responsible physician would consider intraluminally delivering the Ersek … sleeve by catheterization through the vasculature of a lumen, since [its] outwardly projecting edges … would present a clear risk to the patient." D.I. 1370 at 508:7-21; D.I. 1388 at 777:5-778:1. Any attempt to deliver the Ersek device intraluminally "would result in shredding the walls of the body passageway." D.I. 1370 at 508:22-509:14; D.I. 1388 at 778:2-18.

At trial in 2005, Medtronic and BSC both asserted that Ersek could be modified by flattening its sharp outwardly projecting edges, to eliminate any bumps or ridges and make it suitable for intraluminal delivery. That was just a patent lawyer's argument. Of course, Ersek could be "modified" and turned into a stent – one could "modify" a metal tube, a paper clip or a chain-link fence and turn those into stents as well. The problem is there was no reason for anyone to do such a thing.

The Ersek device was not used to treat coronary artery disease or to prevent restenosis or to address any other deficiency of balloon angioplasty. Nor was it intended to treat any condition intraluminally. Indeed, Cordis provided overwhelming evidence that modifying Ersek to eliminate its sharp outwardly projecting edges would defeat Ersek's intended purpose – providing a staple-like device to serve as a substitute for sutures. During the '762 reexamination, the Examiner so found (Ex. O at PWRAP 3257-58):

> [M]aking the outside of the Ersek fixation sleeve smooth rather than rough would be contrary to the teachings of Ersek since the

> rough surface formed by the narrow outwardly projecting edges is intended to embed itself into the tissue wall upon expansion of the sleeve.

See D.I. 1370 at 510:6-511:19; D.I. 1388 at 779:10-781:11. Cordis' expert agreed: "[I]f you take them away and flatten or smooth [Ersek's sharp outwardly projecting edges], you've taken away the whole purpose of Ersek of having this multitude of outwardly projecting edges." *Id.*

This Court has already recognized the fundamental difference: "***stents delivered intraluminally ... and the Ersek fixation sleeve ... are 'disparate devices with no logical connection to one another***.'" D.I. 1251 at 10-11, quoting PWRAP 3061-62 (emphasis added). It is "highly probable" that the jury agreed.

2. The Palmaz Abstract Does Not Disclose Controllable Expansion And Plastic Deformation

The device of the '762 patent is controllably expandable and plastically deformable. Exhibits P and Q. The Palmaz Abstract, on which both defendants rely, does not disclose these features and appears to be just another self-expanding stent. D.I. 1370 at 518:16-519:14; D.I. 1388 at 641:11-642:21. Dr. Palmaz expressly criticized such self-expanding stents in the '762 patent. Ex. P at 1:38-2:8. With these stents, the physician had "no control" over the device's final diameter. D.I. 1370 at 413:10-415:18; D.I. 1388 at 641:11-642:21; *see also* Ex. P at 1:38-2:8. This could have unfortunate consequences. If the expanded diameter was too big, the device could cause "rupturing or tearing" of the artery; if the expanded diameter was too small, the device would not remain in place and could float down the artery, "go[ing] to the wrong place." D.I. 1370 at 387:5-20; *see also* D.I. 1388 at 641:11-642:21.

The Palmaz Abstract is a one-paragraph preview of a eight-minute talk that Dr. Palmaz gave at the Radiological Society of North America (RSNA) conference in 1984. The entire Abstract is reproduced:

3:01 P.M.

993. Expandable Intraluminal Graft: A Preliminary Study

Julio C. Palmaz, M.D., San Antonio, TX, Randy R. Sibbitt, M.D., Stewart R. Reuter, M.D., J.D., Fermin O. Tio, M.D., William J. Rice, M.D.

In an attempt to overcome the problem of restenosis after vascular balloon dilatations, we have developed an expandable intraluminal graft that allows dilatation of the lesion and simultaneous placement of a supportive endoprosthesis to prevent recoil of the arterial wall. The graft is made of continuous, woven, stainless steel wire with soldered cross points. The resulting tubular mesh has a wall thickness of 20–45 microns and a 98% open surface. Eleven grafts of six, eight, and 10 ml in diameter by 20 ml in length were placed in the aorta, common carotid, superior mesenteric, iliac, and renal arteries of dogs. Six grafts showed no stenosis in follow-up studies up to 8.5 weeks. Two grafts had moderate stenosis as a result of neointimal hyperplasia. Two partial and one complete graft thrombosis occurred in nonheparinized animals in which the graft outflow was restricted. No long-term anticoagulation was used. Light and electron microscopy studies showed complete endothelization of the inner surface of the graft at three weeks.

The Abstract describes "an expandable intraluminal graft." With hindsight, we know what Dr. Palmaz would later present at the conference. But the Abstract does not disclose his important ideas. Critically, it does not explain that the expansion is controllable or achieved by plastic deformation. To a reader in 1984, it would appear to describe just another self-expanding stent. As Dr. Buller testified, the Abstract "does not in any sense teach Dr. Palmaz's … control[lable expansion]." D.I. 1371 at 664:4-10; *see also* D.I. 1388 at 789:2-794:21. It "does not disclose any of the important features of Dr. Palmaz's idea. This is a very general description that could equally apply to a spring-type stent," which would not be controllably expandable or plastically deformed. D.I. 1370 at 518:16-519:14; *see also* D.I. 1388 at 793:6-794:4.

No one really disagrees that the Abstract does not disclose controllable expansion or plastic deformation, and so it could not be read to be different than existing self-expanding stents. At trial in 2005, BSC's expert Dr. Snyder agreed that the Abstract "doesn't say anything

... about controllable expansion," and "doesn't say anything about a plastic deformation." D.I. 1372 at 1027:16-1028:14. Following its expert's concessions, all that BSC's counsel could say about the Abstract in his closing argument was the following (D.I. 1373 at 1277:6-9):

> [G]iven the problems that were indicated in the Palmaz abstract, which I'm not going to go into specifically, but they taught this problem of wanting to do that [intraluminal delivery].

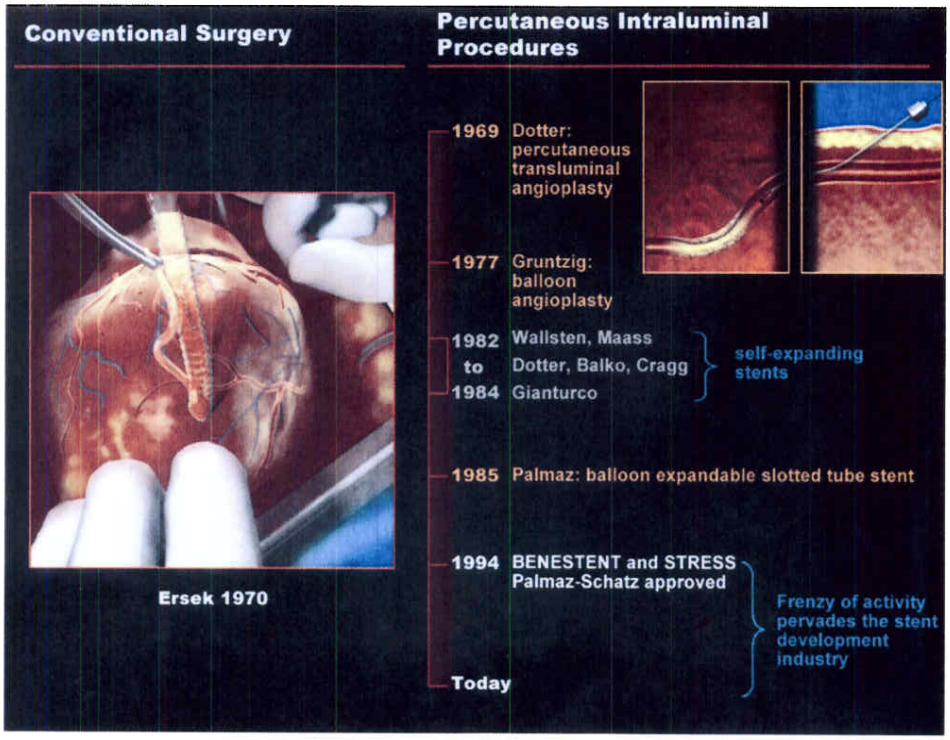
Of course, the Abstract teaches the problem of "wanting to do" intraluminal delivery – but so did Dotter, Gruntzig, Gianturco, et al. None of them solved the problem. Palmaz did. The Abstract's lack of relevance is unrelated to the definition of smooth. There were self-expanding stents that were smooth under any definition, but none taught Palmaz's insight: controllable expansion by plastic deformation. It is "highly probable" that the jury rejected the Abstract for that reason.

Medtronic vaguely asserts the Abstract has supposedly "increased relevance" under the current construction of "smooth" (D.I. 1460 at 14), a contention that deserves special skepticism. This Court may recall that Medtronic obtained the 2005 re-trial, *inter alia*, by offering the same kind of argument – that the Abstract had increased relevance in light of the *Cordis I*'s revised constructions of "slots formed therein" and "substantially uniform thickness." D.I. 1215 at 12. Yet in the ensuing re-trial, Medtronic abandoned reliance on the Abstract altogether. It was not even *mentioned* by any Medtronic witness. The same ruse should not work twice.

* * *

In short, the prior art that defendants claim is now more relevant in light of the claim construction is no more relevant than it was at the trial in 2005. Ersek was not intraluminally deliverable and it came from the entirely alien art of open heart surgery. It was, as the Court concluded, "the antithesis" of Palmaz's invention. Meanwhile, the Abstract, while it

was intraluminally deliverable, was on its face no different than the prior art self-expanding stents, which were not controllably expandable and plastically deformable. Cordis made this point in summation in both cases, using a version of this slide (D.I. 1373 at 1309:3-1317:9; D.I. 1391 at 1869:6-1878:1):



On the left is Ersek, a relic of conventional surgery not remotely suitable for intraluminal use. On the right is the relevant art of intraluminal devices, including the self-expanding stents. The Palmaz abstract is not listed because both defendants largely abandoned it at trial, but it could have been placed in that group as well. Self-expanding stents were intraluminal, but they did not work well. It was Julio Palmaz, working in the art of intraluminal procedures, who made the first advance over Gruntzig, inventing the controllably expandable and plastically deformable stent that could be delivered and expanded by one of Gruntzig's angioplasty balloons. For that he received fame and fortune. It is "highly probable" – essentially a certainty – that that is why both juries rejected the defendants' validity case.

E. For Claim 23, It Is "Highly Probable" that the Current Construction of "Smooth" Would Not Have Altered the Outcome on Obviousness

Medtronic and BSC both argue that they are entitled to new obviousness trials in light of *Cordis II*'s revised construction of "smooth." But overwhelming evidence makes it more than "highly probable" that the outcome would have been the same under the current construction. *See Lewis v. Pinchak*, 348 F.3d 355, 360 (3d Cir. 2003) (finding it highly probable that an error was harmless where the evidence was "overwhelming"); *United States v. Cross*, 308 F.3d 308, 326 (3d Cir. 2002) (same); *Hurley*, 174 F.3d at 112 (same).

The Court can, with great comfort, reject the defendants' position for two interrelated reasons. First, the change in claim construction was "trivial." *Lyon*, 1 F.2d at 49. The Federal Circuit changed the construction from smooth to the touch to smooth enough for intraluminal delivery because it concluded that that was the correct construction and, furthermore, because under the correct construction BSC's stent literally infringed. This meant that the Court did not have to address a complicated doctrine of equivalents issue. But the change is essentially semantics. A stent that is smooth to the touch is suitable for intraluminal delivery; a stent that is suitable for intraluminal delivery is, for all practical purposes, smooth to the touch. If anything, in its emphasis on intraluminal delivery, the change only makes the claim less like Ersek.

Second, the claim term "smooth" was only a peripheral part of the obviousness dispute. Ersek was the "antithesis" of Palmaz because it was designed for open surgery, not intraluminal delivery. That remains true under any definition of smooth. Likewise, the Palmaz abstract was at best just another self-expanding stent. That also remains true under either definition of smooth. These are – it is "highly probable" – the reasons the jury rejected the defendants' obviousness case.

BSC finds significance in Dr. Buller's testimony that the Ersek sleeve has "a multitude of narrow projecting edges" that render it "rough, sharp and certainly not smooth," D.I. 1370 at 506:19-507:8, but that is the same feature that makes the Ersek device not smooth enough for intraluminal delivery under the current construction. Indeed, Dr. Buller made that point immediately after the testimony BSC quotes, agreeing with Dr. Andros's statement that the "outwardly projecting edges" of the Ersek device "would present a clear risk to the patient" so that "[n]o responsible physician would consider intraluminally delivering" the Ersek device. *Id.* at 508:7-21. The testimony on "smooth" that BSC cites was merely cumulative of numerous other distinctions between Ersek and the claimed invention.[2] *See Hurley*, 174 F.3d at 112.

The overwhelming evidence established that Ersek is the "antithesis" of claim 23 because it is not an intraluminal device – under either claim construction.

F. For Claim 44, BSC Has Waived Any Obviousness Challenge

BSC seeks a new trial on obviousness for claim 44 in light of *Cordis I*'s revised construction of "slots formed therein." (This issue only concerns BSC because claim 44 was not asserted against AVE.). But the change in claim scope makes no difference. Ersek had "slots formed therein" under the old construction and the new. BSC twice waived an opportunity to challenge claim 44 and instead, in 2005, praised it as a "great" idea that was entitled to a patent. There is no reason now to permit a new validity trial.

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[2] Other limitations of claim 23 that Dr. Buller described as absent in Ersek included: (a) the requirement of an "expandable *intraluminal* vascular graft," D.I. 1370 at 501:24-502:11; (b) a "wall surface" disposed in a common cylindrical plane, *id.* at 502:12-19; (c) a "substantially uniform thickness," *id.* at 502:20-503:5; (d) "a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen," *id.* at 503:6-17; (e) "a second, expanded and deformed diameter, upon the application of radially outwardly extending force, which is variable and dependent upon the amount of force," *id.* at 503:19-504:7; (f) "[w]hereby the tubular member may be expanded and deformed to [expand] the lumen of body passageway," *id.* at 504:8-16.

BSC argues that this Court should grant a new trial on claim 44 because it granted a new trial on claim 23 in 2005. But there are significant differences between then and now. First, for claim 23, unlike claim 44, there were two claim terms at issue – "slots formed therein" and "substantially uniform thickness." This Court accepted BSC's argument that changes in the construction of those two limitations made the prior art more relevant, principally Ersek, whose lack of a substantially uniform thickness had been a distinguishing feature discussed in the file wrapper. But for claim 44, the only limitation at issue is "slots formed therein." ***Ersek has "slots formed therein" under both the old and new constructions***. The prior art is no more or less relevant than it was when BSC first waived a validity challenge in 2000.

Second, we have now had two validity trials on claim 23. Those trials established that claim 23 is valid and, further, that defendants had misrepresented the supposed significance of the changes in claim construction. The Court more or less said so at the time. D.I. 1391 at 1743:19-1744:9. The benefit of the 2005 trials is that a full record was made of Cordis' proof of nonobviousness, including BSC's concession of the validity of method claims such as claim 44. If claim 23 is nonobvious – and it is – then claim 44, which has many additional limitations, is necessarily nonobvious. Based on the full record, this Court can declare with certainty that it is "highly probable" that the change in claim construction of "slots formed therein" would have no effect whatsoever on the outcome of a validity trial on claim 44.

1. Ersek Has "Slots Formed Therein" Under Both the Old and New Constructions

BSC tells the Court (D.I. 1462 at 21) that *Cordis I*'s revised construction of "slots formed therein" makes Ersek more relevant than it was earlier. The fact is that Ersek is not relevant under either construction for the reasons set forth extensively above – Ersek is a relic of open surgical procedures, not an intraluminal device. But BSC is wrong in any event. Ersek has

"slots formed therein" under both constructions. *Cordis I*'s change in construction of "slots formed therein" did not alter Ersek's relevance (or lack of relevance) and so does not operate to excuse BSC from its waiver.

Early on, this Court construed "slots formed therein" as "limited to devices manufactured by removing material from a preexisting tube to form slots." D.I. 464 at 18. Under that early construction, Ersek did not have "slots formed therein." However, on September 7, 2000, before the first trial, the Court revised that construction construing "slots formed therein" to mean that "[s]lots must be formed in the wall surface of a tubular member, ***as by*** the removal of material." D.I. 790 at 3 (emphasis added). In doing so, it "agree[d] with Cordis … that the material ***need not*** be removed from a preexisting tubular member." *Id.*, at 3, n.4 (emphasis added). This construction made a "preexisting tubular member" and "removal of material" options, rather than required features. The jury was given this construction of "slots formed therein" in the trials in November-December 2000. *See* D.I. 203 (C.A. No. 98-197) at 2743:25-2744:2 ("Slots must be formed in the wall surface of a tubular member as by the removal of material.").

Prior to the 2000 trials, Cordis served supplemental expert reports addressing the revised construction set forth in this Court's September 7, 2000 order. In their supplemental reports, Cordis' experts made a point of stating that Ersek had "slots formed therein" under that construction.

REDACTED

D.I. 1456, Exhibit E at 7. ;

D.I. 1456, Exhibit F at

5. Thus, prior to the 2000 trials, Cordis admitted that Ersek had "slots formed therein" under the construction that governed the 2000 trials.

Yet BSC waived a validity challenge to claim 44 in 2000. When it did so, it had the same ability that it has now to argue that Ersek has "slots formed therein" within the meaning of claim 44. The current construction of "slots formed therein" does not make Ersek any more relevant in this regard and so there is no basis for a new trial.

2. BSC Has Waived an Obviousness Defense to Claim 44 and Conceded its Validity

BSC waived trying the obviousness of claim 44 in 2000 and again in 2005, after the construction of "slots formed therein" was modified. In 2005 it praised the claimed method as valid, indeed "great." BSC does not contend that the reason for its 2000 waiver was reliance on the construction of "slots formed therein" and any such contention would be transparently false. First, of course, Ersek met that claim limitation then, as it does now. But more generally, in 2000, all parties knew what claim constructions had been proposed and understood that there was a risk that the claim constructions would change on appeal. A wavier of a claim – particularly a validity challenge in a patent case – is a serious matter and a party would expect to be bound by that waiver in the future. *Optivus Tech., Inc. v. Ion Beam Applications S.A.*, 469 F.3d 978, 992 (Fed. Cir. 2006). A party that foregoes a validity challenge, knowing the claim construction might change on appeal, has waived that issue. In *CytoLogix*, for example, the Federal Circuit held that when a defendant waived an anticipation defense at trial and did not present substantial evidence on its written description defense, it had waived both defenses when the claim construction was changed on appeal. *CytoLogix Corp. v. Ventana Med. Sys., Inc.*, 424 F.3d 1168, 1175-76 (Fed. Cir. 2005)

During the 2000 trial, BSC failed to present any evidence – let alone substantial evidence – alleging that claim 44 was obvious, and did not ask for a verdict on that issue. Nor did BSC do anything in 2000 to suggest that its waiver of an obviousness challenge was made for reasons of claim construction, rather than trial strategy. And in 2005, when the claim construction had changed, BSC again did not attempt to challenge the validity of claim 44, but rather moved to keep it out of the case. By those actions, BSC waived its ability to rely on obviousness in the event of a changed claim construction.

In fact, BSC's waiver on claim 44 makes complete sense and should not be excused: claim 44 has additional limitations that are not part of claim 23, making it even less susceptible to challenge. BSC's counsel recognized this at trial in 2005, when he told the jury that claim 23 "is not limited to coronaries" and is not "limit[ed] … to a balloon expandable stent." D.I. 1369 at 126:2-10. But these limitations, and others, are found in claim 44. They include: (i) disposing the stent "upon a catheter having an inflatable balloon portion", (ii) delivering it "by percutaneous catheterization", (iii) to a "passageway of a coronary artery having an area of stenosis", (iv) "without surgically exposing the area of the passageway", and (v) expanding and deforming the device "by expanding the inflatable balloon portion of the catheter." Exhibit Q, claim 44.

These additional limitations make method claim 44 much narrower than apparatus claim 23. If claim 23 is nonobvious – and two juries in 2005 applying the current construction of "slots formed therein" so found – then the claim 44 method, with these added limitations, is necessarily not obvious, no matter how "slots formed therein" is construed. D.I. 1369 at 133:8-14; D.I. 1369 at 127:17-128:6; *see* D.I. 1456 at 19-20.

As a result, no party has ever attempted to challenge claim 44 as obvious before a jury. Instead, at the 2005 trial BSC made a strategic decision to try to bolster its obviousness arguments for apparatus claim 23 by telling the jury that the really novel aspect of Dr. Palmaz's work was his *method* of delivering the supposedly obvious apparatus intraluminally, on a balloon catheter. Thus, BSC's counsel told the jury at trial in 2005 that "[Dr. Palmaz's] idea of putting the stent on a balloon, delivering it intraluminally" was a "***great idea***," one that Dr. Palmaz is "entitled to credit for … and he has received it in spades." D.I. 1369 at 127:17-128:6 (emphasis added). BSC's counsel even told the jury, in language that precisely describes claim 44, that ***"Dr. Palmaz is entitled to a patent on the balloon expandable stent, to combine[ ] the expandable stent with a balloon. He's entitled to that."*** D.I. 1369 at 133:8-14 (emphasis added).

If claim 23 is nonobvious – and it is – then claim 44 is nonobvious as a matter of law. No genuine factual dispute can remotely be raised about its validity – and BSC does not attempt to do so now. That is why BSC waived an obviousness challenge in 2000 and affirmatively embraced the validity of the limitations claimed in claim 44 in 2005. The method of fabrication of the stent – the focus of "slots formed therein" – is utterly unrelated to the novelty of the claim. Like claim 23, claim 44's critical features are intraluminal delivery, controllable expansion and plastic deformation, and longitudinal slots. To those patentably distinct limitations, it adds additional features describing the world's first coronary stent deliverable on a balloon. Nothing in the prior art remotely suggests such a combination. It is "highly probable" – indeed certain – that the change in claim construction makes no difference to the validity of claim 44. There is no basis to excuse BSC from its intentional waiver.

3. The Current Construction of "Slots Formed Therein" Is Irrelevant to BSC's Other Arguments

(i) The Revised Construction Does Not Make the Palmaz Abstract Any More Relevant

BSC's assertion (D.I. 1462 at 21-22) that the Palmaz Abstract is more relevant under the revised construction of "slots formed therein" is unconnected to what the record in this case really shows. The most one can say for the Palmaz Abstract is that it is a possible description of one of the self-expanding stents that were known in the art. Most importantly, it does not disclose the controllable expansion and plastic deformation that are features of Dr. Palmaz's invention. The deficiencies that Dr. Buller described in the Abstract's teachings had nothing to do with how "slots" are made, and those deficiencies are the same under the earlier construction and the current construction. Indeed, "slots formed therein" was not even among the many limitations that Cordis relied upon as a basis for distinguishing the Palmaz Abstract when BSC relied on it at trial in 2005. *See* pages 21-23, *supra*.

(ii) BSC Has Twice Waived Its Theory that Dr. Stanley Carson Is a Co-Inventor of the '762 Patent

BSC also argues for claim 44 (but not claim 23) that the revised construction of "slots formed therein" gives it a basis for a new trial on its theory that Dr. Stanley Carson is a co-inventor of the '762 patent. The Carson story, such as it is, is just another bottom-of-the-barrel theory that BSC previously (and wisely) set aside.[3] BSC has twice waived that issue, and its waiver is unaffected by any change in claim construction.

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[3] Dr. Carson was a colleague of Dr. Palmaz in the early 1980s, who introduced Dr. Palmaz to a medical device manufacturer. D.I. 195 (C.A. No. 98-197) at 317:20-322:4. As part of the pre-filing due diligence in 1985, shortly before Dr. Palmaz filed his first patent application, Dr. Carson acknowledged in writing that Dr. Palmaz was "the sole inventor of the expandable intraluminal graft and method … for implanting an expandable intraluminal graft." Dr. Carson

continued . . .

BSC's argument explains precisely why it should not be excused from its waiver. It contends: "Dr. Carson testified that he invented the general concept of intraluminally delivering and expanding a stent on a balloon in an artery, and that Dr. Palmaz's contribution was the specific design of the slotted-tube stent." D.I. 1462 at 26. As this contention makes clear, Dr. Carson's alleged contribution is unrelated to "the specific design of the slotted-tube stent." Thus, whether Dr. Palmaz limited his design to a stent with slots formed by removal of metal from a wall surface, or formed in some other way, has nothing to do with Dr. Carson's supposed inventive contribution. If Dr. Carson contributed to at least one limitation to any claim, he is a co-inventor, however Dr. Palmaz may have chosen to describe his slotted-tube stent. *See Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460-64 (Fed. Cir. 1998). Therefore, the change in scope of "slots formed therein" is unrelated to BSC's ability to claim that Dr. Carson was a co-inventor. It waived that claim twice, once in 2000 and again in 2005.

During the 2000 trial, BSC raised the Carson inventorship issue in its opening statement (D.I. 194 (C.A. No. 98-197) at 152:6-16) and presented Dr. Carson's testimony by videotaped deposition (D.I. 202 (C.A. No. 98-197) at 2286:1-2315:8). It then chose not to seek a verdict on the issue. This waived the issue of Dr. Carson's alleged contributions, regardless of the meaning of "slots formed therein."

. . . continued
also acknowledged that he "ha[d] no right, title, or interest whatsoever in said invention by Dr. Julio C. Palmaz." *Id.*, at 336:5-338:14; D.I. 202 (C.A. No. 98-197) at 2313:21-2314:12; Exhibit R.

The first time Dr. Carson claimed otherwise was a decade later in 1995 – after the Palmaz-Schatz stent had become a commercial success. After Cordis sued a competitor, Cook Inc., for infringement in 1994, Dr. Carson came out of the woodwork, claiming to be a co-inventor and selling his purported rights to Cook, which thereafter settled with Cordis and acknowledged the validity of Dr. Palmaz's invention.

BSC waived the issue again in 2005, after the claim construction had been revised. Although only claim 23 was tried in 2005, that did not limit BSC's ability to claim that Dr. Carson had contributed to claim 44, or to broader method claim 1. Under settled law, Dr. Carson would qualify as a co-inventor if he contributed to at least one limitation of either an asserted or unasserted claim. *See Ethicon, Inc., supra,* 135 F.3d at 1460-64 (holding that Choi was a co-inventor, *inter alia*, because of his contributions to one limitation of an unasserted claim). Instead, BSC waived the issue again. Having twice waived the issue, BSC cannot raise it now. *EEOC v. Westinghouse Elec. Corp.*, 925 F.2d 619, 631 (3d Cir. 1991); *see also USA Petroleum Co. v. Atlantic Richfield Co.,* 13 F.3d 1276, 1280 (9th Cir 1994); *Aircraft Repair Servs. v. Stambaugh's Air Serv.*, 175 F.3d 314, 321-22 (3d Cir. 1999).

IV. There Is No Basis for New Trials on Damages

A. BSC's Assertions on Damages

BSC claims that circumstances have changed since 2000 and that those changed circumstances require a new damages trial. But nothing that has happened in the last seven plus years justifies a new damages trial.

1. Despite Knowing of the Cordis/Medtronic License in 2000, BSC Chose Not to Rely on It

In 2000, BSC ***stipulated*** that Medtronic's stents – including the S series stents – "infringe Claim 23 of the '762 patent, and, therefore, are not noninfringing substitutes." D.I. 209 (C.A. No. 98-197) at 3890:24-3891:2. BSC made that tactical choice in order to avoid the Court informing the jury that Medtronic's Microstent II and GFX stents had just been found to infringe the '762 patent. D.I. 205 (C.A. No. 98-197) at 2836:18-2838:18; D.I. 209 (C.A. No. 98-197) at 3890:24-3891:2.

Having made that stipulation and trying a case to verdict, BSC now wishes to undo its binding stipulation. It now argues that Medtronic's S series stents – the very stents that were the subject of that stipulation – should have been treated as non-infringing products in calculating Cordis' share of the noninfringing market. BSC bases this argument on the fact that long after the 2000 trial, in 2006, an arbitration panel ruled that those stents were licensed under the Palmaz patents in the 1997 Medtronic/Cordis Settlement and License Agreement ("SLA"). But that ruling does not excuse BSC from its stipulation. Cordis produced the SLA to BSC in discovery in 1998. Moreover, BSC used the SLA license at trial, treating other stents licensed under the SLA – such as the Wiktor stent – as noninfringing alternatives. D.I. 209 (C.A. No. 98-197) at 3889:2-5. Had it wished to, BSC was free to raise the license argument in the 2000 trial, just as Medtronic did many years later in the arbitration proceeding. Having enjoyed the benefit of its bargain at trial in 2000, BSC is not entitled to back out of its stipulation to treat the S series stents as infringing products for damages purposes.[4]

2. The ACS Stents Have a "Substantially Uniform Thickness" Under the Revised Construction

BSC asserts that it is entitled to a new trial on whether the ACS stents are noninfringing alternatives. Medtronic has previously pressed the same contention, but has now abandoned it, for good reason. BSC's argument is based on a flagrant falsehood. As set forth in Cordis opening brief (D.I. 1456 at 31-35), in 2000, Cordis established that the ACS stents have a manufacturing tolerance of ranging from 0.00055 to 0.00025 inches for its different stents – far

[4] This Court's May 15, 2002 Memorandum Order (D.I. 1153), which BSC cites (D.I. 1462 at 28, n.14), does not aid its position. In that order, this Court ruled that BSC damages and liability would be held in abeyance "pending the resolution of the appeal of issues concerning Medtronic by the Federal Circuit." D.I. 1153 at 9-10. That appeal and the subsequent Medtronic retrial have restored the Medtronic stents to the status that provided the basis for the damages award in 2000.

below the .001 inch outer limit of the original claim construction and the 100% outer limit of the revised construction.

Recognizing that there is no dispute that the claim limitation is literally infringed, BSC argues that the jury may have misapplied the doctrine of equivalents (DOE). This could not have happened. On the "substantially uniform thickness" limitation, Cordis relied only on ***literal*** infringement for the ACS stents. D.I. 206 (C.A. No. 98-197) at 3217:25-3218:16, 3225:6-3227:6; D.I. 209 (C.A. No. 98-197) at 3793:15-3794:17; D.I. 216 (C.A. No. 98-197) at 3095:10-3096:3. The transcript pages cited by BSC relate to Cordis' DOE proof for a different limitation, "tubular member." *See*, D.I. 206 (C.A. No. 98-197) at 3210, 3212-3218 *cited by* D.I. 1462 at 29. The jury's verdict is a determination that the ACS stents literally infringe the substantially uniform thickness limitation. The jury necessarily found that those stents have a variation of thickness of less than 0.001, which satisfies both the original and modified claim construction.

3. BSC Is Not Entitled to a New Damages Trial Concerning a Theoretical Stent that It Never Designed and Never Made

BSC next argues that a theoretical stent with 100% variations in thickness – which BSC never made, sold or even designed – should qualify as an "available non-infringing substitute." BSC had an opportunity to make that argument during the damages trial in 2000. Having failed to raise the issue then, BSC is not entitled to a new trial to raise it now. *USA Petroleum*, 13 F.3d at 1280; *Westinghouse*, 925 F.2d at 628, 631.

The obvious reason why BSC did not raise this theory in 2000 is that there are no legally sufficient facts to support it. A product cannot qualify as an "available non-infringing alterative" unless it was "available" during the period of infringement. "Acceptable substitutes that … were available during the accounting period [*i.e.*, the period of infringement] can preclude or limit lost profits; ***substitutes only theoretically possible will not."*** *Grain Processing*

Corp. v. American Maize-Prods. Co., 185 F.3d 1341, 1353 (Fed. Cir. 1999) (emphasis added). "[T]he accused infringer has the burden of showing that the alleged alternative was available during th[e] period [of infringement]." *Fiskars, Inc. v. Hunt Mfg. Co.*, 279 F.3d 1378, 1382 (Fed. Cir. 2002). "Technology which is still in development during the [infringement] period is not considered to be an available alternative." *Honeywell Int'l v. Hamilton Sundstrand Corp.*, 166 F. Supp. 2d 1008, 1030 (D. Del. 2001), *aff'd in part, rev'd in part on other grounds*, 370 F.3d 1131 (Fed. Cir. 2004).

The alleged substitute BSC wants to rely upon is "only theoretical[]," if that. *Grain Processing*, 185 F.3d at 1353; *Honeywell*, 166 F. Supp. 2d at 1030. In fact, BSC's theoretical stent, with wall thickness varying 100%, is utterly implausible. As BSC's medical expert Dr. Cumberland explained, stents with "[d]ouble thickness [like BSC's theoretical substitute] … would be like[ly] to cause … platelet aggregation and thrombosis," which would be medically unacceptable. D.I. 1456, Exhibit B at 30-31. Such a product would not have been "acceptable to customers at the time of the infringement." *Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1393 (Fed. Cir. 2003). As a result, this theoretical stent was never "in development." *Honeywell*, 166 F. Supp. 2d at 1030. It did not exist on the drawing board – let alone in the marketplace – during the infringement period. It is a litigation fiction.

Grain Processing, 185 F.3d 1341, does not support BSC's position. In that case, unlike this one, the non-infringing alternative was available during the infringement period – as demonstrated by the fact that in response to the finding of infringement, the infringer was "able to convert to the substitute … process in the remarkably short period of two weeks." *Micro* 318 F.3d at 1123, *citing Grain Processing*, 185 F.3d at 1354. In *Grain Processing*, the Federal Circuit distinguished "available" alternatives from "substitutes [that were] only theoretically

available," and held that the latter cannot qualify as "available, acceptable non-infringing substitutes." *Grain Processing*, 185 F.3d at 1354. That excludes BSC's theoretical stent.

4. There Is No Need for a Damages Trial on Claim 44

BSC also seeks a trial on damages relating to claim 44. However, there is no need for such a trial. If the damages verdict on claim 23 is entered, Cordis cannot and will not seek any additional damages associated with BSC's infringement of the '762 patent.

B. Medtronic's Assertions on Damages

1. Medtronic's JMOL on Lost Profits Damages

Cordis agrees with Medtronic that this Court needs to decide Medtronic's previously filed JMOL on damages filed in 2001 before entering a final judgment. However, there is no need for additional briefing. The issues were fully briefed years ago. To the extent necessary, any new cases could be brought to the Court's attention by a citation of supplemental authority. *See* Local Rule 7.1.2(b). Additional briefing serves no purpose but delay.

2. Medtronic's Concerns over a Possible Invalidity Finding Are Hypothetical

Medtronic also asserts that if, at some point in the future, some court holds claim 23 of the '762 patent invalid, that might effect the damages award. That is simply Medtronic's wishful thinking. No court has ever held claim 23 invalid and Cordis does not believe that any court will ever find it invalid. There is no reason to address that hypothetical concern.

V. Cordis Is Entitled to Prejudgment Interest Based on the Pre-Tax Prime Rate Compounded Monthly

A. Medtronic's "Delay" Argument Lacks Merit

As it has in the past, Medtronic claims Cordis is not entitled to prejudgment interest due to Cordis' alleged delay. Cordis previously briefed this identical argument in D.I. D.I. 1103 at 9-13, which is hereby incorporated by reference. Medtronic itself recognizes its

argument is baseless. Elsewhere, when arguing that the Court should defer entering judgment, Medtronic asserts that "Cordis would not be harmed by any delay" because "pre-judgment interest on past damages will accrue." D.I. 1460 at 17.

B. Prejudgment Interest Should Be Awarded at the Prime Rate Compounded Monthly

As set forth in Cordis' opening brief (D.I. 1456 at 37-39) and Cordis' earlier briefs on entry of judgment (D.I. 1103 at 13-15, D.I. 1412 at 11-13, and D.I. 1421 at 5-8, which are hereby incorporated by reference), the prime rate compounded monthly is the appropriate rate for prejudgment interest, as this Court has already ruled.

The defendants have not offered any compelling reason for this Court to depart from its earlier ruling that it would use prime rate compounded monthly to determine prejudgment interest (D.I. 1456, Ex. L). While the defendants quibble with this Court's earlier rulings – stating that the amount of damages was smaller in that case or it never intended to be bound to that rate – neither offers a persuasive reason why it should be ignored.

C. Prejudgment Interest Should Not Be Based on an After-Tax Interest Rate

As set forth in Cordis' Opening Brief (D.I. 1456 at 39-40) and Cordis' earlier briefs on entry of judgment (D.I. 1103 at 15-17, D.I. 1412 at 12, and D.I. 1421 at 8-9), which is hereby incorporated by reference), prejudgment interest should not be based on the after-tax rate.

The only disputed case cited by defendants that uses an after-tax interest rate is *Alpex Computer Corp. v. Nintendo Co.*, 34 U.S.P.Q.2d 1167 (S.D.N.Y 1994), *aff'd in part on other grounds, rev'd in part*, 102 F.3d 1214 (Fed. Cir. 1996). Seven years after the first time defendants briefed this issue in this case, they have yet to find a disputed case that followed *Alpex* and awarded after-tax interest. Cordis is not aware of any case that follows *Alpex* on this point, and Cordis respectfully submits that this should not be the case to do so.

CONCLUSION

For the reasons set forth above and in Cordis' Opening Brief, this Court should enter final judgment and take the steps needed to finalize a damages award by accounting for BSC's post-verdict sales of the NIR under a formula BSC proposed, and awarding prejudgment interest at the prime rate. On BSC's cross-motion, this Court should not defer further proceedings and should not order a new trial.

ASHBY & GEDDES

/s/ Tiffany Geyer Lydon

Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
Tiffany Geyer Lydon (I.D. #3950)
500 Delaware Avenue - 8th Floor
P.O. Box 1150
Wilmington, DE 19899
302-654-1888

Attorneys for Plaintiff Cordis Corporation

Of Counsel:

Gregory L. Diskant
Eugene M. Gelernter
Michael J. Timmons
Scott B. Howard
Kathleen M. Crotty
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036

Dated: June 23, 2008

EXHIBIT M

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 03-027-SLR
	)	
BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,	)	
	)	
Defendants.	)	

Steven J. Balick, Esq. and John G. Day, Esq. of Ashby & Geddes, Wilmington, Delaware. Of Counsel: Gregory L. Diskant, Esq., William F. Cavanaugh, Esq., Kim J. Landsman, Esq., Rosa E. Sun, Esq. and Catherine A. Williams, Esq. of Patterson, Belknap, Webb & Tyler, LLP, New York, New York.

Josy W. Ingersoll, Esq. and John W. Shaw, Esq. of Young Conaway Stargatt & Taylor, LLP, Wilmington, Delaware. Of Counsel: John Desmarais, Esq. and Peter Armenio, Esq. of Kirkland & Ellis, New York, New York.

MEMORANDUM OPINION

Dated: June 3, 2005
Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

On January 13, 2003, plaintiff Cordis Corporation ("Cordis") filed this patent infringement action against defendants Boston Scientific Corporation and Scimed Life Systems, Incorporated (collectively "BSC") alleging infringement of U.S. Patent No. 4,739,762 ("the '762 patent") by BSC's EXPRESS and TAXUS EXPRESS stents. (D.I. 1) On March 5, 2003, BSC answered and counterclaimed against Cordis, alleging that Cordis' BX VELOCITY, CYPHER, BX SONIC and GENESIS stents infringed U.S. Patent No. 5,922,021 ("the '021 patent"). (D.I. 26) On August 2, 2004, Cordis filed an amended complaint alleging BSC's LIBERTE stent infringed the '762 patent and U.S. Patent No. 5,895,406 ("the '406 patent"). (D.I. 161) On August 18, 2004, BSC answered the amended complaint. (D.I. 163)

This court has jurisdiction pursuant to 28 U.S.C. § 1331. Pending before the court are the parties' motions for summary judgment with respect to infringement of the '762 and '021 patents. (D.I. 216, 219, 225, 226)

II. BACKGROUND

A. The '762 Patent

The '762 patent has been the subject of substantial litigation in this court. In 1998, Cordis sued BSC alleging infringement of the '762 patent by BSC's NIR stent. See Cordis Corp. v. Boston Scientific Corp., 97-550-SLR (D. Del.). A trial

was held in 2000; upon appeal, the Federal Circuit affirmed in part, reversed in part and remanded the case and a subsequent trial was held in March 2005. Id.; Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352 (Fed. Cir. 2003). The court has construed the currently disputed claim limitations. (D.I. 334) In addition, there are several limitations construed by the court in 97-550-SLR that are not in dispute.[1] (D.I. 234)

Cordis alleges BSC's TAXUS, EXPRESS and LIBERTE stents infringe claims 9,[2] 12,[3] 19[4] and 22[5] of the '762 patent, and the EXPRESS AND LIBERTE stents infringe claims 1 and 23 of the '762 patent. (D.I. 230 at 15) Each of these accused devices is a balloon expandable stent. The EXPRESS stent is laser cut from a tube and electropolished. (D.I. 228 at 3-4) It is comprised of connected circular, sinusoidal bands of varying amplitudes.

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[1]The parties do not dispute the court's previous construction of "graft," "prothesis," "tubular member," "plurality of slots formed therein," "wall surface," or "smooth surface." (D.I. 234)

[2]Claim 9 depends from claim 1 as amended by the reexamination certificate. ('762 patent, col. 11, ll. 47-50; '762 reexamination certificate, col. 1, ll. 39-41)

[3]Claim 12 depends from claim 9, which depends from claim 1. ('762 patent, col. 11, ll. 58-61; '762 reexamination certificate, col. 1, ll. 39-41)

[4]Claim 19 depends from claim 23. ('762 reexamination certificate, col. 2, ll. 17-20)

[5]Claim 22 depends from claim 19. ('762 patent, col. 12, ll. 51-54)

(D.I. 262 at 5) The TAXUS stent is an EXPRESS stent with a drug eluting coating. (Id. at 6)

B. The '021 Patent

BSC asserts that the accused Cordis stents infringe claim 36 of the '021 patent. Claim 36 depends from claim 24. ('021 patent, col. 22, l. 42) The court has construed the currently disputed limitations of claims 24 and 36. (D.I. 334)

III. STANDARD OF REVIEW

A court shall grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 n.10 (1986). "Facts that could alter the outcome are 'material,' and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." Horowitz v. Fed. Kemper Life Assurance Co., 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted). If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine

issue for trial.'" Matsushita, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." Pa. Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

IV. DISCUSSION

A. BSC's Motions For Summary Judgment That The LIBERTE Stent Does not Infringe the Palmaz '762 Patent

BSC argues that its LIBERTE stent does not infringe either claim 1 or 23 of the '762 patent because it does not literally, or equivalently,[6] have slots that are substantially parallel to

[6]Because the court finds that there are material issues of fact in dispute with respect to literal infringement by the LIBERTE stent, it also finds that there is evidence from which a reasonable jury could find that the LIBERTE stent infringes under the doctrine of equivalents.

the longitudinal axis of the stent or a biologically inert coating.[7]

A patent is infringed when a person "without authority makes, uses or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a). A court should employ a two-step analysis in making an infringement determination. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995). First, the court must construe the asserted claims to ascertain their meaning and scope. Id. Construction of the claims is a question of law subject to de novo review. See Cybor Corp. v. FAS Techs., 138 F.3d 1448, 1454 (Fed. Cir. 1998). The trier of fact must then compare the properly construed claims with the accused infringing product. Markman, 52 F.3d at 976. This second step is a question of fact. See Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998). Literal infringement occurs where each limitation of at least one claim of the patent is found exactly in the alleged infringer's product. Panduit Corp. v. Dennison Mfg. Co., 836 F.2d 1329, 1330 n.1 (Fed. Cir. 1987). The patent owner has the burden of proving infringement and must meet its

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[7]Cordis alleges that the LIBERTE stent infringes claims 9, 12, 19 and 22 of the '762 patent. Because all of these claims depend from either claim 1 or claim 23 of the '762 patent, if the LIBERTE stent does not infringe claims 1 or 23, it cannot infringe the claims asserted against it. See Whapeton Canvas Co., Inc. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed. Cir. 1989).

burden by a preponderance of the evidence. SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed Cir. 1988) (citations omitted).

1. Substantially Parallel Slots

Claims 1 and 23 require that a stent have "slots being disposed substantially parallel to the longitudinal axis of the tubular member." As construed by the court, "a 'slot' is a long and narrow opening or groove, an opening whose length is substantially greater than its width." (D.I. 334) "[T]he claim also requires slots in the tubular members that run largely or approximately parallel to the longitudinal axis." (Id.) BSC asserts that the slots of the LIBERTE stent cannot be substantially parallel to the longitudinal axis because they intersect the longitudinal axis of the stent at between 30 and 90 degree angles. (D.I. 223 at 11) Cordis argues that the slots of the LIBERTE stent are banana shaped slots with a direction of elongation that is parallel to the longitudinal axis.

Based on the current record, a reasonable jury could conclude that the slots of the LIBERTE stent are banana shaped, as opposed to two straight slots as argued by BSC. (D.I. 223 at 6) Such banana shaped slots would be "slots," as construed by the court, because they are long, narrow openings whose length is substantially greater than its width. (D.I. 334)

To meet the limitations of claims 1 and 23, these banana shaped slots do not have to be exactly parallel to the longitudinal axis, but only "largely or approximately" parallel. The banana shaped slots of the LIBERTE stent could be considered largely or approximately parallel to the longitudinal axis because they run along the longitudinal axis. Cordis has provided expert deposition testimony that one of ordinary skill in the art would regard the LIBERTE slots as substantially parallel to the longitudinal axis because the "overall effect" is that slots are directionally elongated parallel to the longitudinal axis. (D.I. 258, Ex. 5 at 55, 202) For these reasons, there are material issues of fact with respect to the slots of the LIBERTE stent. BSC's motion for summary judgment is denied in this regard.

2. Biologically Inert Coating

Claims 9 and 19 of the '762 patent require that a stent have a "biologically inert coating." As construed by the court, a "biologically inert coating" is "a coating that is not biologically active." (D.I. 334) BSC argues that the drug-eluting coating of the LIBERTE stent cannot be "biologically inert." Cordis asserts that the polymer, SIBS, that coats the LIBERTE stent is biologically inert and merely carries the drug, therefore, one could conclude that the coating of the LIBERTE stent is biologically inert.

Cordis has provided evidence showing that one of ordinary skill in the art might consider SIBS, by itself, to be the coating of the LIBERTE stent. Dr. Buller states that the SIBS polymer does not have a biological activity. (D.I. 259, Ex. 5 at 94) According to Dr. Buller, the drug and the polymer coating do not interact and the drug is only present in discrete patches. (Id. at 92, 95) Dr. Storey also testified to this effect. (Id., Ex. 8) A jury could credit either, or both, of these expert opinions and determine that the coating of the LIBERTE stent is biologically inert. For this reason, BSC's motion for summary judgment is denied in this regard.

B. Cordis' Motion For Summary Judgment That the EXPRESS And TAXUS Stents Infringe The '762 Patent

Cordis argues that the EXPRESS and TAXUS stents meet all the limitations of claims 1 and 23 of the '762 patent. BSC contends that these accused stents do not meet the "thin-walled," "substantially uniform thickness," or "smooth surface" limitations of claim 1, as construed by the court. BSC also asserts that the accused stents do not meet the "wall surface" limitation of claim 23.

1. Claim 1 Of The '762 Patent

Claim 1 of the '762 patent requires that a stent be thin-walled. As construed by the court, "thin-walled" requires that "the wall of the tubular member must have little extent from one surface to its opposite at both its first and second diameters."

(D.I. 334)[8] BSC has offered evidence that one of ordinary skill in the art would consider a stent with "little extent" to be "around 3 or 4/1000 of an inch." (D.I. 262, Ex. M at 161-62) The accused stents have a wall thickness of approximately 0.0052 inches, i.e., thicker than that considered of "little extent" by one of ordinary skill. Therefore, there are genuine issues of material fact. Cordis' motion for summary judgment is denied in this regard.

2. Claim 23 Of The '762 Patent

Claim 23 requires that a stent have a "wall surface." As construed by the court, "wall surface" requires that "the outer surface of the tubular member must be disposed in a common cylindrical plane." (D.I. 234, citing 97-550-SLR, D.I. 1127)[9] BSC has provided evidence that the accused stents may not have a

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[8]BSC argues that the court should reconstrue its construction of "thin-walled" to exclude struts that are thicker than they are wide, as Dr. Palmaz disclaimed such subject matter during prosecution of the '762 patent. (D.I. 262 at 10-11) The court declines to reconsider its claim construction.

[9]Cordis argues that this limitation applies only to a stent in its first diameter. Nothing in the court's construction, however, requires that the wall surface be disposed in a common cylindrical plane only in its first diameter. The claim itself discusses both the first and second diameter of the stent. ('762 patent, col. 12, ll. 3-13) The court disagrees with Cordis that the prosecution history of the '762 patent requires that "wall surface" apply only to the stent in the first diameter. The portion of the prosecution history cited by Cordis merely references the stent in the first diameter in conjunction with a common cylindrical plane, but does not require that the wall surface limitation only apply in the first diameter. (D.I. 262, Ex. A at PWRAP 3054)

wall surface on a common cylindrical plane, as the unconnected peaks of the stent flare out upon expansion. (D.I. 262 at 11, Ex. K at 182-83) For this reason, there are genuine issues of material fact. Cordis' motion for summary judgment is denied in this regard.

C. Cordis' Motion For Summary Judgment That Its Accused Stents Do Not Infringe Claim 36 Of The '021 Patent

Cordis argues that claim 23, as properly construed, does not include stents that are 180 degrees out of phase, as such subject matter was disclaimed by the patentees during prosecution when they amended claim 23 to add the "wherein" limitation. BSC argues that when properly construed, claim 23 does not exclude stents that are 180 degrees out of phase. According to BSC, there was no clear disclaimer of subject matter during prosecution of the '021 patent.

1. Literal Infringement

With respect to the "wherein" limitation, the court adopted neither of the parties' constructions. Instead, the court adopted the ordinary meaning of the limitation, finding support for such an interpretation in both the specification and the prosecution history. (D.I. 334) Because Cordis did not present any evidence that its accused stents do not meet the "wherein" limitation, as construed by the court, its motion for summary judgment is denied with respect to literal infringement.

2. Infringement Under The Doctrine Of Equivalents

Cordis argues that BSC cannot assert a doctrine of equivalents argument because the patentees of the '021 patent narrowed claim 23 by adding the "wherein" limitation by amendment in response to the examiner's rejection.

The doctrine of equivalents is limited by the doctrine of prosecution history estoppel. In Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722 (2002), the Supreme Court stated:

> Prosecution history estoppel ensures that the doctrine of equivalents remains tied to its underlying purpose. Where the original application once embraced the purported equivalent but the patentee narrowed his claims to obtain the patent or to protect its validity, the patentee cannot assert that he lacked the words to describe the subject matter in question. The doctrine of equivalents is premised on language's inability to capture the essence of innovation, but a prior application describing the precise element at issue undercuts that premise. In that instance the prosecution history has established that the inventor turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter.

Id. at 734-735. In other words, the prosecution history of a patent, as the public record of the patent proceedings, serves the important function of identifying the boundaries of the patentee's property rights. Once a patentee has narrowed the scope of a patent claim as a condition of receiving a patent, the patentee may not recapture the subject matter surrendered.

In order for prosecution history estoppel to apply, however, there must be a deliberate and express surrender of subject matter. See Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1580 (Fed. Cir. 1995).

During prosecution of the '021 patent, the examiner rejected claim 23 as anticipated by a Pinchasik patent application. (D.I. 233, Ex. 25) According to the examiner, a figure in Pinchasik disclosed the subject matter in claim 23. (Id. at JFH 192) The examiner attached to the rejection a modified Pinchasik figure, referencing where the limitations of claim 23 could be found. (Id. at JFH 195) The examiner and patentee had an interview. (Id. at JFH 203) The patentees then added the following language to claim 23: "[W]herein the first expansion strut of the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column." (Id. at JFH 208) According to the patentees, their invention had "a first expansion strut of a first expansion strut pair in a first expansion column that has a longitudinal axis which is offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in a second expansion column," a structure not taught or suggested by Pinchasik. (Id. at JFH 209)

After the amendment the examiner rejected all the claims due to double patenting. The examiner explained that Patent Application No. 08/824,142 claimed expansion columns "wherein the first column loop slots are non-parallel or non-collinear to the second column loop slots. The application also claims that the first expansion strut in the first expansion column is circumferentially offset from a corresponding second expansion strut of the second expansion column." (Id. at JFH 217) The patentees filed a terminal disclaimer and their claims issued as the '021 patent. (Id. at JFH 225-26)

In this case, the court finds that there has not been a clear surrender of subject matter. The patentees' statements in response to the rejection dealt with what the prior art did not disclose, as opposed to what their invention did not include, and it is not clear that they gave up any subject matter with these statements. Likewise, it is not clear that the associated amendment narrowed the claim, as opposed to making the claim more clearly state what the invention was. See Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1220 (Fed. Cir. 1995) ("[W]hen claim changes or arguments are made in order to more particularly point out the applicant's invention, the purpose is to impart precision, not to overcome prior art . . ., such prosecution is not presumed to raise an estoppel . . . ."). Therefore, the court finds that prosecution history estoppel does not apply and

Cordis' motion for summary judgment is denied with respect to infringement by equivalents.

V. CONCLUSION

For the reasons stated, BSC's motions for summary judgment that the LIBERTE stent does not infringe the '762 patent (D.I. 219, 225) are denied. Cordis' motion for summary judgment of infringement (D.I. 226) is denied. Cordis' motion for summary judgment of noninfringement of the '021 patent (D.I. 216) is denied. An order consistent with this memorandum opinion shall issue.

EXHIBIT N

Appeal Nos. 2008-1003, -1072

United States Court of Appeals

for the

Federal Circuit

CORDIS CORPORATION,

Plaintiff-Appellant,

– v. –

BOSTON SCIENTIFIC CORPORATION
and SCIMED LIFE SYSTEMS, INC.,

Defendants-Cross Appellants.

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF DELAWARE IN CASE NO. 03-CV-027,
JUDGE SUE L. ROBINSON

BRIEF FOR DEFENDANTS-CROSS APPELLANTS

JOHN M. DESMARAIS
PETER J. ARMENIO
YOUNG J. PARK
TIMOTHY K. GILMAN
KIRKLAND & ELLIS LLP
Citigroup Center
153 East 53rd Street
New York, New York 10022
(212) 446-48001

Attorneys for Defendants-Cross Appellants

May 12, 2008

> So certainly, ***if I say you cannot bring it up in this [NIR] case, there cannot be a waiver***, and certainly, if I say you can't bring it up in this case, I can't imagine that although I don't know for sure, ***but I would find it difficult to think from a common-sense standpoint that the findings here are preclusive in the Express case . . . . So I mean, I don't think Cordis can have it both ways.***

(A8885/15:25-16:7) It was not until after the 2005 NIR retrial that Cordis first asserted collateral estoppel and the district court precluded BSC from ever raising the Monograph as a prior art reference.

This exclusion was error for at least four reasons. First, there was no "prior judgment." Even today, the NIR validity judgment is on remand for consideration of a new trial in light of the broadened construction of "smooth surface." *Cordis*, 511 F.3d at 1180. Notably, this is the same limitation that Dr. Buller asserted was not disclosed by the 1980 version of the Monograph. (A19580/263:17-265:6)

Second, Cordis waived collateral estoppel by never pleading it as an affirmative defense to BSC's declaratory judgment claim for invalidity. *Arizona v. California*, 530 U.S. 392, 410 (2000) ("[R]es judicata [is] an affirmative defense ordinarily lost if not timely raised.").

Third, BSC did not have a "full and fair" opportunity to litigate the Monograph issue in the NIR case since the district court precluded BSC from presenting it in that action. *See, e.g., In re Freeman*, 30 F.3d 1459, 1467 (Fed. Cir.

EXHIBIT O

v.

CORDIS CORPORATION, JOHNSON & JOHNSON, and EXPANDABLE GRAFTS PARTNERSHIP,

Counterclaim Defendants.

MEDTRONIC AVE, INC.,

Plaintiff,

v.

CORDIS CORPORATION, JOHNSON & JOHNSON, and EXPANDABLE GRAFTS PARTNERSHIP,

Defendants.

C.A. No. 97-700-SLR

BOSTON SCIENTIFIC CORPORATION,

Plaintiff,

v.

ETHICON, INC.; CORDIS CORPORATION; and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO.,

Defendants.

Civil Action No. 98-19-SLR

FILE HISTORY FOR U.S. PATENT 4,739,762
(Reexamination No. 90/004,785) (Vol. 3)
JOINTLY SUBMITTED ON BEHALF OF CORDIS CORPORATION, BOSTON SCIENTIFIC CORPORATION, SCIMED LIFE SYSTEMS, INC. AND MEDTRONIC AVE, INC.

Dated: April 4, 2000

By: _____
Josy W. Ingersoll (I.D. #1088)
Christian Douglas Wright (I.D. #3554)

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

[redacted]

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DM21/0825

[illegible] P MILNAMOW
DRESSLER ROCKEY MILNAMOW & KATZ LTD
[illegible] STETSON SUITE 4700
[illegible] IL 60601

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#22

3731

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08/25/98

NOTICE OF INTENT TO ISSUE REEXAMINATION CERTIFICATE

1. [X] Examination has been terminated in this reexam proceeding and a Certificate will be issued in due course in view of:
   - a. [X] Patent owner's communication filed on: 7/8/98, 7/22/98, 8/13/98 8/18/98 & 8/24/98
   - b. [ ] Patent owner's late response filed on: ______
   - c. [ ] Patent owner's failure to file an appropriate response to the Office action dated: ______
   - d. [ ] Patent owner's failure to timely file an Appeal Brief. 37 C.F.R. 1.192.
   - e. [ ] Other: ______

   The Reexamination Certificate will indicate the following:

   - f. Change in the Specification: [X] Yes, [ ] No
   - g. Change in the Drawings: [ ] Yes, [X] No
   - h. Status of the Claims:
     - (1) Patent claim(s) confirmed: 23, 34
     - (2) Patent claim(s) amended: 1-12, 14-22, 25-33 35-43
     - (3) Patent claim(s) cancelled: 13, 24
     - (4) New claim(s) patentable: 44-59

2. [X] Note attached statement of reasons for patentability and/or confirmation. Any comments considered necessary by patent owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submissions should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation."

3. [X] Note attached NOTICE OF REFERENCES CITED, PTO - 892, which is a part of this communication. The listed references are considered pertinent to the claimed invention, but the claims are deemed to be patentable thereover.

4. [X] Note attached LIST OF REFERENCES CITED, PTO - 1449, which is part of this communication and serves as an acknowledgment of receipt of patent owner's prior art statement. The references which were considered have been initialed on the form by the examiner and the claims are deemed patentable thereover.

5. [ ] The drawing correction request filed on ______: [ ] is, [ ] is not, approved.

6. [ ] Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has: [ ] been received, [ ] not been received, [ ] been filed in Serial No. ______ filed on ______.

7. [X] Note Examiner's Amendment (attachment).

8. [ ] Other (attachment).

cc: Requester

PWRAP 003252

PTOL-469 (2-90)

area of stenosis for substantially the same reasons as those given above.

Claims 23 and 34

Claims 23 and 34 have not been amended. These claims were rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Ersek (3,657,744). This rejection is no longer considered to be proper. Each of these claims includes the limitation "wherein the outside of the wall surface of the tubular member is a smooth surface when the tubular member has the first diameter". Upon reconsideration, the outside of the wall surface of the Ersek (3,657,744) fixation sleeve is not considered to be smooth. The Ersek fixation sleeve is formed of expanded metal. A sample of conventional expanded metal was shown to the examiner during the July 8, 1998 interview. The sample is depicted in Exhibit 1 of the July 22, 1998 amendment. The sample has the same basic shape as that shown in figure 5 of Ersek. As one follows the outside surface of one of the strands of the sample, one meets an abrupt obstacle at the bridge (at the junction of the strands) since the bridge has a thickness which is twice as great as the strand. The outside of the wall surface of the Ersek fixation sleeve includes a multitude of these obstacles (one at each bridge), making it rough rather than smooth. Therefore, the Ersek reference fails to meet the smooth surface limitation quoted above. Further, making the outside of the Ersek

fixation sleeve smooth rather than rough would be contrary to the teachings of Ersek since the rough surface formed by narrow outwardly projecting edges is intended to embed itself into the tissue wall upon expansion of the sleeve (col. 3, lines 1-6).

Claims 35 and 37

Claims 35 and 37 have been amended. These claims, prior to the amendment, were rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarus (4,787,899) in view of Ersek (3,657,744). These claims were also rejected under 35 U.S.C. 103(a) as being unpatentable over Kononov (U.S.S.R. 660,689) in view of Ersek (3,657,744). These rejections are no longer considered to be proper. Amended claims 35 and 37, like unamended claims 23 and 34, include the limitation "wherein the outside of the wall surface of the tubular member is a smooth surface when the tubular member has the first diameter". Ersek fails to meet this limitation as indicated above. Even if an Ersek type of fixation sleeve were placed on the Lazarus or Kononov graft, its outside wall surface would not be smooth as claimed.

Claims 35 and 37, prior to the amendment, were also rejected under 35 U.S.C. 103(a) based upon Kononov in view of Kornberg (4,617,932). This rejection is no longer considered to be proper. Claims 35 and 37 include the limitation "the wall surface having a substantially uniform thickness". Even if the Kornberg type of struts 12 were included in the Kononov prosthesis, the prosthesis

In Conclusion

As indicated above, none of the claims can be properly rejected using the same references and grounds of rejection applied in the first Office Action. No other combination of these references can be used to properly reject any of the claims as they now stand. In addition to these references, all of the other references of record have been carefully considered. None of the references of record, whether considered separately or in any combination, can be used to properly reject any of the claims as they now stand.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981.

mht
August 25, 1998

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731

EXHIBIT P

United States Patent [19]

Palmaz

[11] **Patent Number: 4,739,762**

[45] **Date of Patent: Apr. 26, 1988**

[54] **EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT**

[75] Inventor: **Julio C. Palmaz, San Antonio, Tex.**

[73] Assignee: **Expandable Grafts Partnership, San Antonio, Tex.**

[21] Appl. No.: **923,798**

[22] Filed: **Nov. 3, 1986**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 796,009, Nov. 7, 1985.

[51] **Int. Cl.**[4] **A61M 29/00**

[52] **U.S. Cl.** **128/343; 604/104; 604/96; 623/1**

[58] **Field of Search** ..... 604/93, 49, 343, 97; 623/2; 128/344, 343, 1 R

[56] **References Cited**

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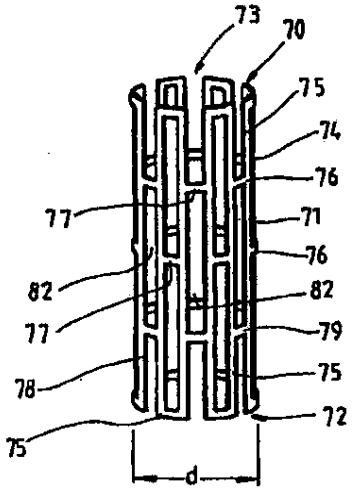
Primary Examiner—C. Fred Rosenbaum
Assistant Examiner—Gene B. Kartchner
Attorney, Agent, or Firm—Ben D. Tobor

[57] **ABSTRACT**

An expandable and deformable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel. The graft may be a thin-walled tubular member having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular member.

43 Claims, 2 Drawing Sheets



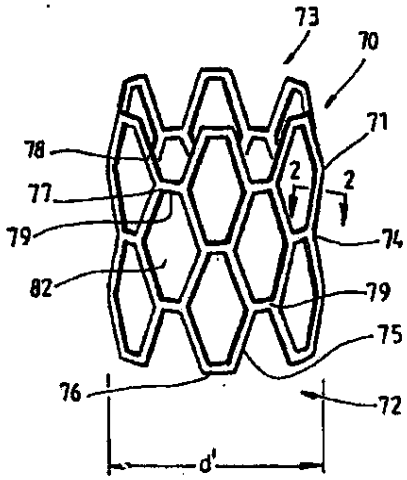


Fig. 2

Fig. 1B

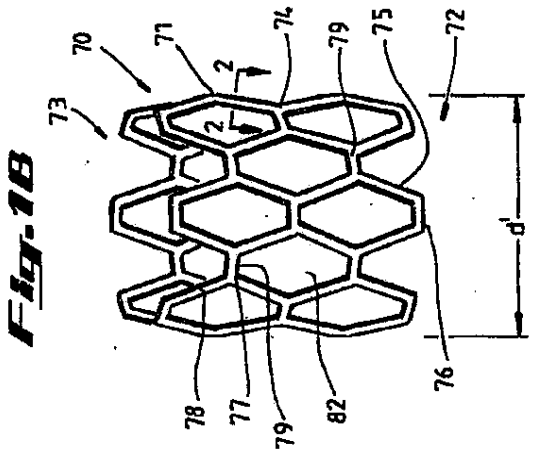


Fig. 1A

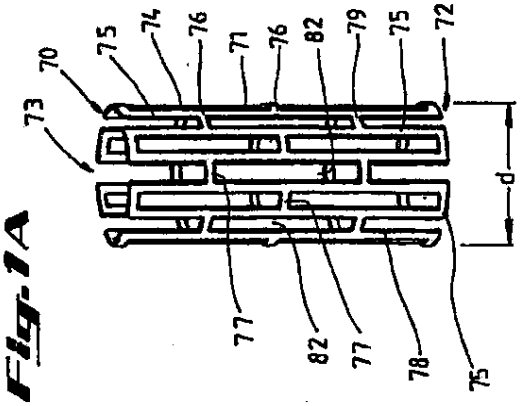
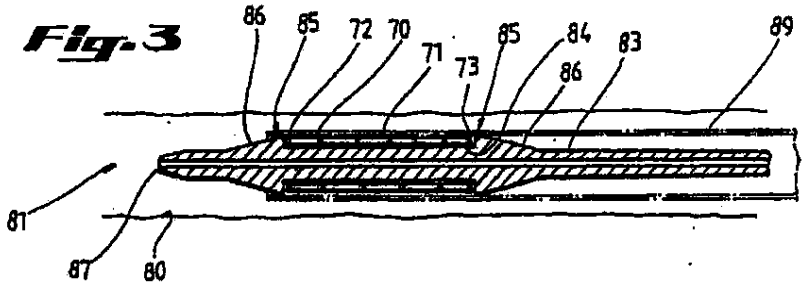


Fig. 3



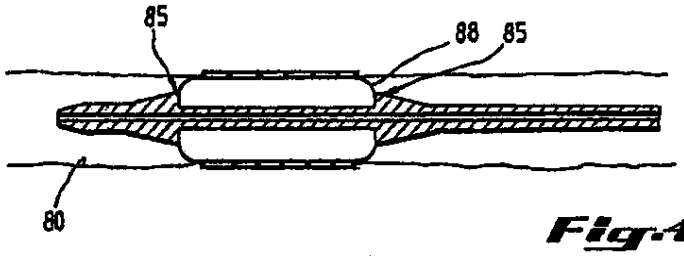
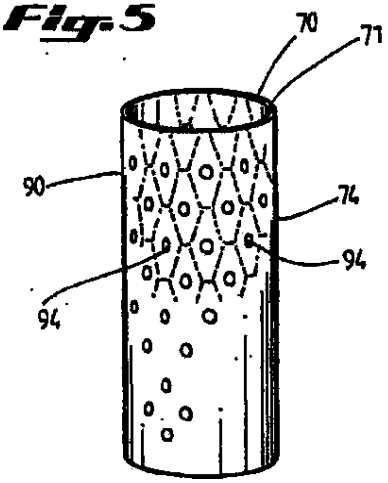


Fig. 4

Fig. 5



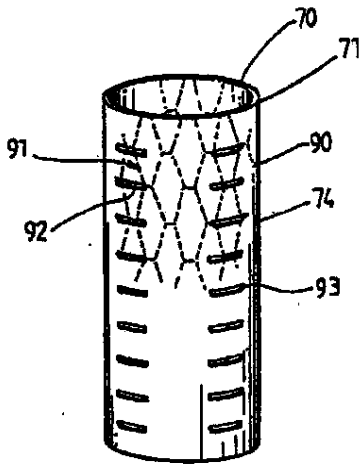


Fig. 6

EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT

RELATED APPLICATION

This application is a continuation-in-part of Applicant's co-pending application Ser. No. 06/796,009 filed Nov. 7, 1985 entitled Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft.

FIELD OF THE INVENTION

The invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraluminal grafts.

DESCRIPTION OF THE PRIOR ART.

Intraluminal endovascular grafting has been demonstrated by experimentation to present a possible alternative to conventional vascular surgery. Intraluminal endovascular grafting involves the percutaneous insertion into a blood vessel of a tubular prosthetic graft and its delivery via a catheter to the desired location within the vascular system. Advantages of this method over conventional vascular surgery include obviating the need for surgically exposing, incising, removing, replacing, or bypassing the defective blood vessel.

Structures which have previously been used as intraluminal vascular grafts have included coiled stainless steel springs; helically wound coil springs manufactured from an expandable heat-sensitive material; and expanding stainless steel stents formed of stainless steel wire in a zig-zag pattern. In general, the foregoing structures have one major disadvantage in common. Insofar as these structures must be delivered to the desired location within a given body passageway in a collapsed state, in order to pass through the body passageway, there is no effective control over the final, expanded configuration of each structure. For example, the expansion of a particular coiled spring-type graft is predetermined by the spring constant and modulus of elasticity of the particular material utilized to manufacture the coiled spring structure. These same factors predetermined the amount of expansion of collapsed stents formed of stainless steel wire in a zig-zag pattern. In the case of intraluminal grafts, or prostheses, formed of a heat sensitive material which expands upon heating, the amount of expansion is likewise predetermined by the heat expansion characteristics of the particular alloy utilized in the manufacture of the intraluminal graft.

Thus, once the foregoing types of intraluminal grafts are expanded at the desired location within a body passageway, such as within an artery or vein, the expanded size of the graft cannot be changed. If the diameter of the desired body passageway has been miscalculated, an undersized graft might not expand enough to contact the interior surfact of the body passageway, so as to be secured thereto. It may then migrate away from the desired location within the body passageway. Likewise, an oversized graft might expand to such an extent that the spring force, or expansion force, exerted by the graft upon the body passageway could cause rupturing of the body passageway. Further, the constant outwardly radiating force exerted upon the interior surface of the body passageway can cause erosion of the internal surface, or intima, of the artery or body passageway.

Another alternative to conventional vascular surgery has been percutaneous balloon dilation of elastic vascular stenoses, or blockages, through use of a catheter mounted angioplasty balloon. In this procedure, the angioplasty balloon is inflated within the stenosed vessel, or body passageway, in order to shear and disrupt the wall components of the vessel to obtain an enlarged lumen. With respect to arterial atherosclerotic lesions, the relatively incompressible plaque remains unaltered, while the more elastic medial and adventitial layers of the body passageway stretch around the plaque. This process produces dissection, or a splitting and tearing, of the body passageway wall layers, wherein the intima, or internal surface of the artery or body passageway, suffers fissuring. This dissection forms a "flap" of underlying tissue which may reduce the blood flow through the lumen, or block the lumen. Typically, the distending intraluminal pressure within the body passageway can hold the disrupted layer or flap, in place. If the intimal flap created by the balloon dilation procedure is not maintained in place against the expanded intima, the intimal flap can fold down into the lumen and close off the lumen, or may even become detached and enter the body passageway. When the intimal flap closes off the body passageway, immediate surgery is necessary to correct this problem.

Although the balloon dilation procedure is typically conducted in the catherization lab of a hospital, because of the foregoing problem, it is always necessary to have a surgeon on call should the intimal flap block the blood vessel or body passageway. Further, because of the possibility of the intimal flap tearing away from the blood vessel and blocking the lumen, balloon dilations cannot be performed upon certain critical body passageways, such as the left main coronary artery, which leads into the heart. If an intimal flap formed by a balloon dilation procedure abruptly comes down and closes off a critical body passageway, such as the left main coronary artery, the patient could die before any surgical procedures could be performed.

Additional disadvantages associated with balloon dilation of elastic vascular stenoses is that many fail because of elastic recoil of the stenotic lesion. This usually occurs due to a high fibrocollagenous content in the lesion and is sometimes due to certain mechanical characteristics of the area to be dilated. Thus, although the body passageway may initially be successfully expanded by a balloon dilation procedure, subsequent, early restenosis can occur due to the recoil of the body passageway wall which decreases the size of the previously expanded lumen of the body passageway. For example, stenoses of the renal artery at the ostium are known to be refractory to balloon dilation because the dilating forces are applied to the aortic wall rather than to the renal artery itself. Vascular stenoses caused by neointimal fibrosis, such as those seen in dialysis-access fistulas, have proved to be difficult to dilate, requiring high dilating pressures and larger balloon diameters. Similar difficulties have been observed in angioplasties of graft-artery anastomotic strictures and postendar-

terectomy recurrent stenoses. Percutaneous angioplasty of Takayasu arteritis and neurofibromatosis arterial stenoses may show poor initial response and recurrence which is believed due to the fibrotic nature of these lesions.

Accordingly, prior to the development of the present invention, there has been no expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway, which: prevents recurrence of stenoses in the body passageway; can be utilized for critical body passageways, such as the left main coronary artery of a patient's heart; prevents recoil of the body passageway wall; and allows the intraluminal graft to be expanded to a variable size to prevent migration of the graft away from the desired location; and to prevent rupturing and/or erosion of the body passageway by the expanded graft. Therefore, the art has sought an expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway which: prevents recurrence of stenoses in the body passageway; is believed to be able to be utilized in critical body passageways, such as the left main coronary artery of the heart; prevents recoil of the body passageway; and can be expanded to a variable size within the body passageway to prevent migration of the graft away from the desired location; and to prevent rupturing and/or erosion of the body passageway by the expanded graft.

SUMMARY OF THE INVENTION

In accordance with the invention the foregoing advantages have been achieved through the present expandable intraluminal vascular graft. The present invention includes a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the walls surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; the tubular shaped member having a first diameter which permits intraluminal delivery of the thin-walled tubular member into a body passageway having a lumen; and the tubular member having a second, expanded diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular shaped member may be expanded and deformed to expand the lumen of the body passageway.

A further feature of the present invention is that the slots may be uniformly and circumferentially spaced from adjacent slots and the slots may be uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots. Another feature of the present invention is that each slot may have first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member. An additional feature of the present invention is that the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter. A further feature of the present invention is that the tubular shaped member may have a biological inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway.

In accordance with the invention, the foregoing advantages have also been achieved through the present method for implanting a prosthesis within a body passageway. The method of the present invention comprises the steps of: utilizing a thin-walled, tubular member as the prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; disposing the prosthesis upon a catheter; inserting the prosthesis and catheter within the body passageway by catheterization of said body passageway; and expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway, the prosthesis being deformed beyond its elastic limit.

A further feature of the present invention is that the portion of the catheter in contact with the prosthesis may be collapsed, and the catheter removed from the body passageway. A further feature of the present invention is that a catheter having an expandable, inflatable portion associated therewith may be utilized; and expansion of the prosthesis and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

A further feature of the present invention is that the slots may be uniformly and circumferentially spaced from adjacent slots and the slots may be uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots. Another feature of the present invention is that each slot may have first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

In accordance with the invention, the foregoing advantages have also been achieved through the present apparatus for intraluminally reinforcing a body passageway. The present invention includes: an expandable and deformable, thin-walled tubular prosthesis having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the prosthesis; and a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable and deformable tubular prosthesis on the expandable, inflatable portion, whereby upon inflation of the expandable, inflatable portion of the catheter, the prosthesis is expanded and deformed radially outwardly into contact with the body passageway. A further feature of the present invention is that the mounting and retaining means may comprise a retainer ring member disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable and deformable tubular prosthesis.

The expandable intraluminal vascular graft, method for implanting a prosthesis within a body passageway, and apparatus for intraluminally reinforcing a body passageway of the present invention, when compared with previously proposed prior art intraluminal grafts, methods for implanting them, and balloon dilation techniques have the advantages of: preventing recurrence of

stenoses; is believed to permit implantation of grafts in critical body passageways, such as in the left main coronary artery of the heart; prevents recoil of the body passageway; prevents erosion of the body passageway by the expanded graft; and permits expansion of the graft to a variable size dependent upon conditions within the body passageway.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1A is a perspective view of an expandable intraluminal vascular graft, or prosthesis for a body passageway, having a first diameter which permits delivery of the graft, or prosthesis, into a body passageway;

FIG. 1B is a perspective view of the graft, or prosthesis, of FIG. 1A, in its expanded configuration when disposed within a body passageway;

FIG. 2 is a cross-sectional view of the prosthesis taken along line 2–2 of FIG. 1B;

FIG. 3 is a cross-sectional view of an apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, illustrating a prosthesis, or intraluminal vascular graft, in the configuration shown in FIG. 1A;

FIG. 4 is a cross-sectional view of the apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, with the graft, or prosthesis, in the configurations shown in FIG. 1B; and

FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon.

While the invention will be described in connection with the preferred embodiment, it will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents, as may be included within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE INVENTION:

In FIGS. 1A and 1B, an expandable intraluminal vascular graft, or expandable prosthesis for a body passageway, 70 is illustrated. It should be understood that the terms "expandable intraluminal vascular graft" and "expandable prosthesis" are interchangeably used to some extent in describing the present invention, insofar as the methods, apparatus, and structures of the present invention may be utilized not only in connection with an expandable intraluminal vascular graft for expanding partially occluded segments of a blood vessel, or body passageway, but may also be utilized for many other purposes as an expandable prosthesis for many other types of body passageways. For example, expandable prostheses 70 may also be used for such purposes as: (1) supportive graft placement within blocked arteries opened by transluminal recanalization, but which are likely to collapse in the absence of an internal support; (2) similar use following catheter passage through mediastinal and other veins occluded by inoperable cancers; (3) reinforcement of cathether created intrahepatic communications between portal and hepatic veins in patients suffering from portal hypertension; (4) supportive graft placement of narrowing of the esophagus, the intestine, the ureters, the urethra; and (5) supportive graft reinforcement of reopened and previously obstructed bile ducts. Accordingly, use of the term "prosthesis" encompasses the foregoing usages within various types of body passageways, and the use of the term "intraluminal vascular graft" encompasses use for expanding the lumen of a body passageway. Further, in this regard, the term "body passageway" encompasses any duct within the human body, such as those previously described, as well as any vein, artery, or blood vessel within the human vascular system.

Still with reference to FIGS. 1A and 1B, the expandable intraluminal vascular graft, or prosthesis, 70 is shown to generally comprise a tubular member 71 having first and second ends 72, 73 and a wall surface 74 disposed between the first and second ends 72, 73. Tubular member 71 has a first diameter, d, which, to be hereinafter described in greater detail, permits intraluminal delivery of the tubular member 71 into a body passageway 80 having a lumen 81 (FIG. 3). With reference to FIG. 1B, upon the application from the interior of the tubular member 71 of a radially, outwardly extending force, to be hereinafter described in greater detail tubular member 71 has a second, expanded diameter, d', which second diameter d' is variable in size and dependent upon the amount of force applied to deform the tubular member 71.

Tubular member 71, may be any suitable material which is compatible with the human body and the bodily fluids (not shown) with which the vascular graft, or prosthesis, 70 may come into contact. Tubular member 71 must also be made of a material which has the requisite strength and elasticity characteristics to permit the tubular member 71 to be expanded and deformed from the configuration shown in FIG. 1A to the configuration shown illustrated in FIG. 1B and further to permit the tubular member 71 to retain its expanded and deformed configuration with the enlarged diameter d' shown in FIG. 1B and resist radial collapse. Suitable materials for the fabrication of tubular member 71 would include silver, tantalum, stainless steel, gold, titanium or any suitable plastic material having the requisite characteristics previously described.

Preferably, tubular member 71 is initially a thin-walled stainless steel tube having a uniform wall thickness, and a plurality of slots 82 are formed in the wall surface 74 of tubular member 71. As seen in FIG. 1A when tubular member 71 has the first diameter d, the slots 82 are disposed substantially parallel to the longitudinal axis of the tubular member 71. As seen in FIG. 1A, the slots 82 are preferably uniformly and circumferentially spaced from adjacent slots 82, as by connecting members 77, which connecting members 77 preferably have a length equal to the width of slots 82, as seen in FIG. 1A. Slots 82 are further uniformly spaced from adjacent slots 82 along the longitudinal axis of the tubular member 71, which spacing is preferably equal to the width of connecting members 77. Thus, the formation of slots 82 results in at least one elongate member 75 being formed between adjacent slots 82, elongate member 75 extending between the first and second ends, 72, 73 of tubular member 71, as seen in FIG. 1A.

Still with reference to FIG. 1A, each slot will have first and second ends with a connecting member 77 disposed at the first and second ends of slots 82. Preferably, the first and second ends of each slot 82 are disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Thus, connecting members 77, which are disposed at the first and second ends of each slot 82, and between elongate members 75, will in turn be disposed

intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Accordingly, slots 82 are preferably uniformly and circumferentially spaced from adjacent slots, and slots 82 adjacent to one another along the longitudinal axis of tubular member 71 are in a staggered relationship with one another. Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of tubular member 71 will only have a length equal to approximately one-half of the length of a complete slot 82, such half-slot 82 being bounded by members 78, 79, at both the first and second ends 72, 73 of tubular member 71. Although the graft, or prosthesis, 70 of FIGS. 1A and 1B is illustrated to have a length approximately equal to the length of two slots 82, it should be apparent that the length of the graft 70 could be made longer or shorter as desired. Use of the term "slot" encompasses an opening whose length is substantially greater than its width, such as an elongated oval opening.

The foregoing described construction of graft, or prothesis, 70 permits graft, or prothesis, 70 to be expanded uniformly, and outwardly, into the configuration shown in FIG. 1B, upon the application of a suitable force from the interior of tubular member 71, as will be hereinafter described in greater detail. The expansion of tubular member 71 into the configuration shown in FIG. 1B is further uniform along the length of tubular member 71, not only because of the uniform spacing between slots 82, as previously described, but also because the thickness of the wall surface 74, or the thickness of connecting members 77, elongate members 75, and members 78, 79, is the same uniform thickness. As illustrated in FIG. 2, the uniform thickness of elongate member 75 is shown, and the preferred cross-sectional configuration of elongate member 75, connecting member 77, and members 78, 79, is illustrated, which configuration is rectangular. It should of course be understood by those skilled in the art, that the cross-sectional configuration of the foregoing components of graft, or prothesis, 70 could also be square. As will be hereinafter described in greater detail, it is preferable that the outer surface 74 of graft, or prothesis, 70, which would be in contact with the body passageway 80 FIG. 4), should be relatively smooth.

With reference to FIG. 1B, it is seen that after the graft, or prothesis 70, has been expanded and deformed into the configuration of FIG. 1B, the slots 82 will assume a substantially hexagonal configuration when the tubular member 71 has the second, expanded diameter, d', as shown in FIG. 1B. Such a hexagonal configuration will result when the slots 82 initially have a substantially rectangular configuration when the tubular member 71 has the first diameter, d, illustrated in FIG. 1A. It should be noted that were the width of slots 82 to be substantially reduced, whereby the length of connecting member 77 would approximate a single point intersection, the expansion of such a tubular member 71 would result in slots 82 assuming a configuration which would be substantially a parallelogram (not shown).

It should be noted that not only is tubular member 71 expanded from the configuration shown in FIG. 1A to achieve the configuration shown in FIG. 1B, but tubular member 71 is further "deformed" to achieve that configuration. By use of the term "deformed" is meant that the material from which graft, or prothesis, 70 is manufactured is subjected to a force which is greater than the elastic limit of the material utilized to make tubular member 71. Accordingly, the force is sufficient to permanently bend elongate members 75 whereby segments of the elongate members 75 pivot about connecting members 77 and move in a circumferential direction as they pivot, whereby the diameter of the tubular member 71 increases from the first diameter, d, to the expanded diameter, d', of FIG. 1B. The force to be applied to expand tubular member 71, which is applied in the manner which will be hereinafter described in greater detail, must thus be sufficient to not only expand tubular member 71, but also to deform elongate member 75, in the manner previously described, whereby the portions of the elongate members 75 which pivot about the ends of connecting members 77 do not "spring back" and assume their configuration shown in FIG. 1A, but rather retain the configuration thereof in FIG. 1B. Once graft, or prothesis, 70 has been expanded and deformed into the configuration shown in FIG. 1B, graft, or prothesis 70, will serve to prevent a body passageway from collapsing as will be hereinafter described in greater detail. It should be noted that when tubular member 71 has the first diameter, d, shown in FIG. 1A, or after tubular member 71 has been expanded and deformed into the second, expanded diameter, d', of FIG. 1B, tubular member 71 does not exert any outward, radial force, in that tubular member 71 is not a "spring-like" or "self-expanding member", which would tend to exert an outwardly radial force.

With reference now to FIGS. 3 and 4, the methods and apparatus of the present invention will be described in greater detail. Once again, it should be understood that the methods and apparatus of the present invention are useful not only for expanding the lumen of a body passageway, such as an artery, vein, or blood vessel of the human vascular system, but are also useful to perform the previously described procedures to intraluminally reinforce other body passageways or ducts, as previously described. Still with reference to FIGS. 3 and 4, an expandable intraluminal vascular graft, or prosthesis, 70, of the type described in connection with FIGS. 1A and 1B, is disposed or mounted upon a catheter 83. Catheter 83 has an expandable, inflatable portion 84 associated therewith. Catheter 83 includes means for mounting and retaining 85 the expandable intraluminal vascular graft, of prosthesis, 70 on the expandable, inflatable portion 84 of catheter 83. Preferably, the mounting and retaining means 85 comprises retainer ring members 86 disposed on the catheter 83 adjacent the expandable inflatable portion 84 of catheter 83; and a retainer ring member 86 is disposed adjacent each end 72, 73 of the expandable intraluminal vascular graft, or prosthesis, 70. Preferably, as seen in FIG. 3, retainer ring members are formed integral with catheter 83, and the retainer ring member 86 adjacent the leading tip 87 of catheter 83 slopes upwardly and away from catheter tip 87 in order to protect and retain graft or prosthesis, 70 as it is inserted into the lumen 81 of body passageway 80, as to be hereinafter described in greater detail. The remaining retainer ring member 86 as shown in FIG. 3, slopes downwardly away from tip 87 of catheter 83, to insure easy removal of catheter 83 from body passageway 80. After expandable intraluminal graft, or prosthesis, 70 has been disposed upon catheter 83, in the manner previously described, the graft, or prosthesis, 70 and catheter 83 are inserted within a body passageway 80 by catheterization of the body passageway 80 in a conventional manner.

In a conventional manner, the catheter 83 and graft, or prosthesis, 70 are delivered to the desired location within the body passageway 80, whereat it is desired to expand the lumen 81 of body passageway 80 via intraluminal graft 70, or where it is desired to implant prosthesis 70. Fluoroscopy, and/or other conventional techniques may be utilized to insure that the catheter 83 and graft, or prosthesis, 70 are delivered to the desired location within the body passageway. Prosthesis, or graft, 70 is then expanded and deformed by expanding the expandable, inflatable portion 84 of catheter 83, whereby the prosthesis, or graft, 70 is expanded and deformed radially, outwardly into contact with the body passageway 80, as shown in FIG. 4. In this regard, the expandable, inflatable portion of catheter 83 may be a conventional angioplasty balloon 88. After the desired expansion and deformation of prosthesis, or graft, 70 has been accomplished, angioplasty balloon 88 may be collapsed, or deflated, and the catheter 83 may be removed in a conventional manner from body passageway 80. If desired, as seen in FIG. 3, catheter 83, having graft or prosthesis, 70 disposed thereon, may be initially encased in a conventional Teflon TM sheath 89, which is pulled away from prosthesis, or graft, 70, prior to expansion of the prosthesis, or graft, 70.

Still with reference to FIGS. 3 and 4, it should be noted that tubular member 71 of prosthesis, or graft, 70 initially has the first predetermined, collapsed diameter, d, as described in connection with FIG. 1A, in order to permit the insertion of the tubular member, 71 into the body passageway 80 as previously described. When it is desired to implant prosthesis 70 within a body passageway 80 for the purposes previously described, the prosthesis 70 is expanded and deformed to the second diameter, d', and the second, expanded diameter, d', is variable and determined by the internal diameter of the body passageway 80, as shown in FIG. 4. Accordingly, the expanded and deformed prosthesis 70, upon deflation of angioplasty balloon 88 will not be able to migrate from the desired location within the body passageway 80, nor will the expansion of the prosthesis 70 be likely to cause a rupture of the body passageway 80. Furthermore, insofar as prosthesis, or graft, 70 is not a "spring-like" or "self-expanding member", the prosthesis is not consistently applying an outward, radial force against the interior surface of body passageway 80 in excess of that required to resist radial collapse of the body passageway 80. Thus, erosion of the interior surface, or intima, of the artery or body passageway is prevented.

When it is desired to use expandable intraluminal graft 70 to expand the lumen 81 of a body passageway 80 having an area of stenosis, the expansion of intraluminal vascular graft 70 by angioplasty balloon 88, allows controlled dilation of the stenotic area and, at the same time controlled expansion and deformation of the vascular graft 70, whereby vascular graft 70 prevents the body passageway 80 from collapsing and decreasing the size of the previously expanded lumen 81. Once again, the second, expanded diameter d' of intraluminal vascular graft 70, as shown in FIG. 4, is variable and determined by the desired expanded internal diameter of body passageway 80. Thus, the expandable intraluminal graft 70 will not migrate away from the desired location within the body passageway 80 upon deflation of angioplasty balloon 88, nor will the expansion of intraluminal graft 70 likely cause a rupture of body passageway 80, nor any erosion as previously described. Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80. In the situation of utilizing graft 70 in the manner previously described to expand the lumen of a portion of a critical body passageway, such as the left main coronary artery, it is believed that the intimal flap will be unable to occlude the left main coronary artery of the heart and cause the death of the patient.

Because it is only necessary to inflate angioplasty balloon 88 one time in order to expand and deform graft 70, it is believed that a greater amount of endothelium, or inner layer of the intima, or inner surface of the body passageway, will be preserved, insofar as the extent of endothelial denudation during transluminal angioplasty is proportional to the balloon inflation time. Further, in theory, the amount of preserved endothelium should be large because in the expanded configuration of graft 70, potentially 80% of the endothelium is exposed through the openings or expanded slots 82 of graft 70. It is further believed that intact patches of endothelium within expanded slots 82 of graft 70 may result in a rapid, multicentric endothelialization pattern as shown by experimental studies.

With reference now to FIGS. 5 and 6, prostheses, or grafts, 70 of the type previously described in connection with FIGS. 1A and 1B are shown, and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials. The coating 90 should be thin and highly elastic so as not to interfere with the desired expansion and deformation of prosthesis, or graft, 70. Coating 90 may be further provided with a means for anchoring 91 (FIG. 6) the tubular member 71 to the body passageway 80. Anchoring means 91 may be comprised of a plurality of radially, outwardly extending projections 92 formed on the coating 90. As seen in FIG. 6, the radially outwardly extending projections 92 could comprise a plurality of ridges 93, or other types of radially, outwardly extending projections. Further, it may be desirable to have a plurality of openings 94 formed in coating 90, as shown in FIG. 5, whereby the fluid contained in body passageway 80 can be in direct contact with the dilated, or expanded, body passageway area.

It is to be understood that the invention is not limited to the exact details of construction, operation, exact materials or embodiment shown and described, as obviously modifications and equivalents will be apparent to one skilled in the art. For example, the means for expanding the prosthesis or graft could be a plurality of hydraulically actuated rigid members disposed on a catheter, or a plurality of angioplasty balloons could be utilized to expand the prosthesis or graft. Accordingly, the invention is therefore to be limited only by the scope of the appended claims.

I claim:

1. A method for implanting a prosthesis within a body passageway comprising the steps of:

utilizing a thin-walled, tubular member as the prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

disposing the prosthesis upon a catheter;

inserting the prosthesis and catheter within the body passageway by catheterization of said body passageway; and

expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway, the prosthesis being deformed beyond its elastic limit.

2. The method of claim 1, further including the steps of: collapsing the portion of the catheter associated with the prosthesis, and removing the catheter from the body passageway.

3. The method of claim 1, including the steps of: utilizing a catheter having an expandable, inflatable portion associated therewith; and the expansion and deformation of the prosthesis and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

4. The method of claim 1, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

5. The method of claim 4, wherein each slot has first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

6. The method of claim 5, wherein the thin-walled tubular member and the elongate members disposed between adjacent slots have a uniform wall thickness.

7. The method of claim 1, wherein the thin-walled tubular member is expanded and deformed to a second diameter within the body passageway; the second, expanded diameter being variable and determined by the internal diameter of the body passageway, whereby the expanded thin-walled tubular member will not migrate from the desired location within the body passageway and the expansion of the thin-walled tubular member does not cause a rupture of the body passageway.

8. The method of claim 7, wherein the thin-walled tubular member is uniformly, outwardly expanded and deformed along its length.

9. The method of claim 1, wherein the thin-walled tubular member is provided with a biologically inert coating on the outer surface of the thin-walled tubular member.

10. The method of claim 9, wherein the coating is provided with a means for anchoring the prosthesis to the body passageway.

11. The method of claim 10, wherein the means for anchoring is the coating being provided with a plurality of radially, outwardly extending projections for engagement with the body passageway.

12. The method of claim 9, wherein the coating is provided with a plurality of openings to allow communication between the body passageway and the interior of the thin-walled tubular member.

13. An expandable intraluminal vascular graft, comprising:

a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

14. The expandable intraluminal vascular graft of claim 13, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

15. The expandable intraluminal vascular graft of claim 14, wherein each slot has first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

16. The expandable intraluminal vascular graft of claim 13, wherein the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter.

17. The expandable intraluminal vascular graft of claim 13, wherein the slots have a substantially rectangular configuration when the tubular member has the first diameter, and the slots have a substantially hexagonal configuration when the tubular member has the second, expanded diameter.

18. The expandable intraluminal vascular graft of claim 13, wherein the slots have a configuration which is substantially a parallelogram after the tubular member has been expanded and deformed into the second expanded diameter.

19. The expandable intraluminal vascular graft of claim 13, wherein the tubular member has a biologically inert coating on the wall surface.

20. The expandable intraluminal vascular graft of claim 19, wherein the coating includes a means for anchoring the tubular member to the body passageway.

21. The expandable intraluminal vascular graft of claim 20, wherein the anchoring means is a plurality of radially, outwardly extending projections formed on the coating.

22. The expandable intraluminal vascular graft of claim 19, wherein the coating has a plurality of openings therein to allow communication between the body passageway and the interior of the tubular member.

23. The expandable intraluminal vascular graft of claim 13, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.

24. An expandable prosthesis for a body passageway, comprising:

a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

25. The expandable prosthesis for a body passageway of claim 24, wherein the tubular member has a biologically inert coating on the wall surface.

26. The expandable prosthesis for a body passageway of claim 25, wherein the coating includes a means for anchoring the tubular member to the body passageway.

27. The expandable prosthesis for a body passageway of claim 26, wherein the anchoring means is a plurality of radially, outwardly extending projections formed on the coating.

28. The expandable prosthesis for a body passageway of claim 25, wherein the coating has a plurality of openings therein to allow communication between the body passageway and the interior of the tubular member.

29. The expandable prosthesis of claim 24, wherein the the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

30. The expandable prosthesis of claim 29, wherein each slot has first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

31. The expandable prosthesis of claim 24, wherein the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter.

32. The expandable prosthesis of claim 24, wherein the slots have a substantially rectangular configuration when the tubular member has the first diameter; and the slots have a substantially hexagonal configuration when the tubular member has the second, expanded diameter.

33. The expandable prosthesis of claim 24, wherein the slots have a configuration which is substantially a parallelogram after the tubular member has been expanded and deformed into the second expanded diameter.

34. The expandable prosthesis of claim 24, wherein the outside of the wall surface, of the tubular member is a smooth surface, when the tubular member has the first diameter.

35. An apparatus for intraluminally reinforcing a body passageway, comprising:

an expandable and deformable, thin-walled tubular prosthesis having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the prosthesis; and

a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, thin-walled tubular prosthesis on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the prosthesis is expanded and deformed radially outwardly into contact with the body passageway.

36. The apparatus of claim 35, wherein the mounting and retaining means comprises retainer ring members disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable, tubular prosthesis.

37. An apparatus for expanding the lumen of a body passageway comprising:

an expandable and deformable thin-walled intraluminal vascular graft having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the graft; and

a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, deformable intraluminal vascular graft on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the intraluminal vascular graft is expanded and deformed radially outwardly into contact with the body passageway.

38. The apparatus of claim 37, wherein the mounting and retaining means comprises retainer ring members disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable intraluminal vascular graft.

39. The method of claim 1, wherein tantalum is utilized for the tubular member.

40. The expandable intraluminal vascular graft of claim 13, wherein tantalum is utilized for the tubular member.

41. The expandable prosthesis of claim 24, wherein tantalum is utilized for the tubular member.

42. The apparatus of claim 35, wherein tantalum is utilized for the tubular prosthesis.

43. The apparatus of claim 37, wherein tantalum is utilized for the intraluminal vascular graft.

* * * * *

EXHIBIT Q

US004739762B1

REEXAMINATION CERTIFICATE (3650th)

United States Patent [19]

Palmaz

[11] B1 4,739,762

[45] Certificate Issued Oct. 27, 1998

[54] **EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT**

[75] Inventor: **Julio C. Palmaz**, San Antonio, Tex.

[73] Assignee: **Expandable Grafts Partnership**, San Antonio, Tex.

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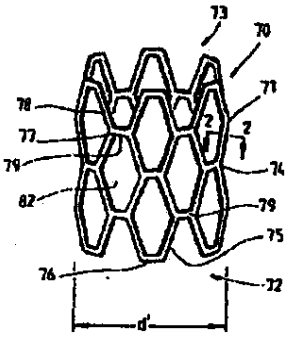
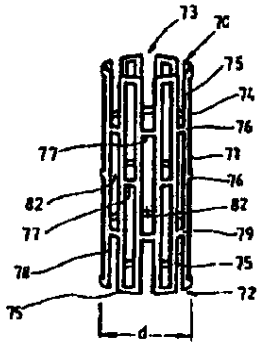
Primary Examiner—Michael H. Thaler

[57] **ABSTRACT**

An expandable and deformable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel. The graft may be a thin-walled tubular member having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular member.





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REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

ONLY THOSE PARAGRAPHS OF THE SPECIFICATION AFFECTED BY AMENDMENT ARE PRINTED HEREIN.

Column 7, after line 20:

With reference to FIGS. 1A and 1B, it is seen that certain of the slots 82 formed in tubular member 71 are open ended slots. The circumferentially adjacent slots 82, whether open ended or closed, define ring portions that are defined by a plurality of peak portions and valley portions. In the preferred embodiment, the ring portions at the first and second ends 72, 73 are not in phase with each other. Also in the preferred embodiment, open ended slots are defined by a pair of spaced apart elongate members 75 that are connected together by a connecting member 77 that extends between one end of each of the elongate members 75.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims 23 and 34 is confirmed.

Claims 13 and 24 are cancelled.

Claims 1, 14, 16–19, 25, 29, 31–33, 35, 37, 40 and 41 are determined to be patentable as amended.

Claims 2–12, 15, 20–22, 26–28, 30, 36, 38, 39, 42 and 43, dependent on an amended claim, are determined to be patentable.

New claims 44–59 are added and determined to be patentable.

1. A method for implanting a prosthesis within a body passageway comprising the steps of:

utilizing a thin-walled, tubular member as the prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

disposing the prosthesis upon a catheter;

inserting the prosthesis and catheter within the body passageway by catheterization of said body passageway; and

expanding and deforming the prosthesis at [a desired] *the* location *of an existing natural obstruction* within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway, the prosthesis being deformed beyond its elastic limit.

14. The expandable intraluminal vascular graft of claim [13] *23*, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

16. The expandable intraluminal vascular graft of claim [13] *23*, wherein the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter.

17. The expandable intraluminal vascular graft of claim [13] *23*, wherein the slots have a substantially rectangular configuration when the tubular member has the first diameter; and the slots have a substantially hexagonal configuration when the tubular member has the second, expanded diameter.

18. The expandable intraluminal vascular graft of claim [13] *23*, wherein the slots have a configuration which is substantially a parallelogram after the tubular member has been expanded and deformed into the second expanded diameter.

19. The expandable intraluminal vascular graft of claim [13] *23*, wherein the tubular member has a biologically inert coating on the wall surface.

25. The expandable prosthesis for a body passageway of claim [24] *34*, wherein the tubular member has a biological inert coating on the wall surface.

29. The expandable prosthesis of claim [24] *34*, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjcent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

31. The expandable prosthesis of claim [24] *34*, wherein the tubular member does not exert any outward, radial force while the tubular member has the first or second expanded diameter.

32. The expandable prosthesis of claim [24] *34*, wherein the slots have a substantially rectangular configuration when the tubular member has the first diameter, and the slots have a substantially hexagonal configuration when the tubular member has the second, expanded diameter.

33. The expandable prosthesis of claim [24] *34*, wherein the slots have a configuration which is substantially a parallelogram after the tubular member has been expanded and deformed intop the second expanded diameter.

35. An apparatus for intraluminally reinforcing a body passageway, comprising:

an expandable and deformable, thin-walled tubular prosthesis having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a *substantially uniform thickness and a* plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the prosthesis, *the prosthesis having a first diameter which permits intraluminal delivery of the prosthesis into a body passageway having a lumen and wherein the outside of the wall surface of the prosthesis is a smooth surface when the prosthesis has the first diameter*; and

a catheter having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, thin-walled tubular prosthesis on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the prosthesis is expanded and deformed radially outwardly into contact with the body passageway.

37. An apparatus for expanding the lumen of a body passageway comprising:

an expandable and deformable thin-walled intraluminal vascular graft having first and second ends, and a wall

surface disposed between the first and second ends, the wall surface having a *substantially uniform thickness and a* plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the graft, *the vascular graft having a first diameter which permits intraluminal delivery of the graft into a body passageway having a lumen and wherein the outside of the wall surface of the graft is a smooth surface when the graft has the first diameter*; and

a catheter having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, deformable intraluminal vascular graft on the expandable, inflatable portion.

whereby upon inflation of the expandable, inflatable portion of the catheter, the intraluminal vascular graft is expanded and deformed radially outwardly into contact with the body passageway.

40. The expandable intraluminal vascular graft of claim [13] *23*, wherein tantalum is utilized for the tubular member.

41. The expandable prosthesis of claim [24] *34*, wherein tantalum is utilized for the tubular member.

44. A method for implanting a balloon expandable stent prosthesis within a passageway of a coronary artery having an area of stenosis, comprising the steps of:

utilizing a thin-walled, tubular member as the stent prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

disposing the stent prosthesis upon a catheter having an inflatable balloon portion;

inserting the stent prosthesis and catheter within the passageway by percutaneous catheterization;

delivering the catheter and stent prosthesis to the area of stenosis without surgically exposing the area of the passageway; and

expanding and deforming the stent prosthesis at the area of stenosis within the coronary artery passageway by expanding the inflatable balloon portion of the catheter associated with the stent prosthesis to force the stent prosthesis radially outwardly into contact with the area of stenosis in the passageway, the stent prosthesis being controllably deformed beyond its elastic limit.

45. The method of claim 44 wherein at least certain of the slots are defined by a pair of spaced apart elongate members that are connected together at one end of each of the elongate members so as to define an open ended slot.

46. The method of claim 44, wherein said tubular member includes at least one ring portion defined by circumferentially adjacent slots so as to define a plurality of peak portions and valley portions.

47. The method of claim 46, wherein said tubular member has a first end and a second end and includes one of said ring portions at said first and second ends thereof.

48. The method of claim 46, wherein the tubular member is formed from a plastically deformable material.

49. The method of claim 46, wherein the stent prosthesis after expansion has mechanical strength sufficient to provide radial support of the body passageway and prevent migration of the stent prosthesis within the body passageway.

50. The method of claim 46, wherein the tubular member has an outer wall surface and the slots formed in the outer wall surface upon expansion of the tubular member define open areas of approximately eighty percent (80%) of the area of the wall surface.

51. In combination, a balloon expandable stent prosthesis for implantation in the passageway of a coronary artery having an area of stenosis and a catheter, comprising:

an expandable stent prosthesis being a thin-walled tubular member having first and second ends and a wall having an outer wall surface disposed between the first and second ends, the wall having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member,

a catheter having an expandable, inflatable balloon portion;

the tubular member being disposed on the balloon portion of the catheter;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member and the catheter into a lumen of a coronary artery having an area of stenosis and wherein the outside of the wall surface of the tubular member is a smooth surface when the tubular member has the first diameter; and

the tubular member having a second, expanded and deformed diameter upon the application from the interior of the tubular member of radially, outwardly extending force, by inflating the balloon portion of the catheter, which second diameter is variable and controlled by the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the coronary artery in the area of stenosis.

52. The combination of claim 51, wherein at least certain of the slots are defined by a pair of spaced apart elongate members that are connected together at one end of each of the elongate members so as to define an open ended slot.

53. The combination of claim 52, wherein a connecting member extends between and connects said one end of each of the elongate strut members.

54. The combination of claim 51, wherein said tubular member includes at least one ring portion defined by circumferentially adjacent slots so as to define a plurality of peak portions and valley portions.

55. The combination of claim 54, wherein said tubular member includes one of said ring portions at its first and second ends.

56. The balloon expandable stent prosthesis of claim 55, wherein the ring portions at the first and second ends are not in phase with each other.

57. The combination of claim 51, wherein the tubular member is formed of a plastically deformable material.

58. The combination of claim 51, wherein the tubular member in its second, expanded diameter has mechanical strength sufficient to provide radial support of the coronary artery and prevent migration of the tubular member from the area of stenosis.

59. The combination of claim 51, wherein the slots formed in the wall surface of the tubular member in its second, expanded diameter define open areas of approximately eighty percent (80%) of the area of the wall surface.

* * * * *

EXHIBIT R

November 15, 1985

Dr. Julio C. Palmaz
12610 Stone Hinge
San Antonio, Texas 78230

Dear Julio:

The purpose of this letter is to let you know that I acknowledge, represent and warrant that you are the sole inventor of the EXPANDABLE INTRALUMINAL GRAFT AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT, and that I have no right, title, or interest whatsoever in said invention. By Dr. Julio C. Palmaz.

Sincerely,

11-18-85

Stanley Carson, M.D.

Def's EXHIBIT 1-B FOR I.D.
DATE 8-3-95
DEPO OF Stanley Carson, M.D.
Sheri D. Stoner, C.S.R.

PLAINTIFF'S EXHIBIT 1098

DEPOSITION EXHIBIT 87 Palmaz